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Legislative Assembly of Ontario

Second Session, 40th Parliament

Assemblée législative de l'Ontario

Deuxième session, 40^e législature

Official Report of Debates (Hansard)

Monday 25 February 2013



Journal des débats (Hansard)

Lundi 25 février 2013

**Standing Committee on
Social Policy**

Organization

**Comité permanent de
la politique sociale**

Organisation

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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 25 February 2013

Lundi 25 février 2013

The committee met at 1405 in committee room 1.

ELECTION OF CHAIR

The Clerk of the Committee (Mr. William Short): Good afternoon, honourable members. My name is William Short. I'm the Clerk of the Standing Committee on Social Policy.

I call upon you today to elect a Chair. Are there any nominations?

Ms. Cheri DiNovo: Yes. I'd like to nominate Uncle Ernie Hardeman as our Chair.

The Clerk of the Committee (Mr. William Short): Mr. Hardeman, do you accept the nomination?

Mr. Ernie Hardeman: I accept the nomination, but I would ask the Clerk to take the "uncle" off.

The Clerk of the Committee (Mr. William Short): All right. I can do that.

Mr. Ernie Hardeman: We only use that at home around the dinner table.

The Clerk of the Committee (Mr. William Short): Okay. Any further nominations for Chair?

Seeing none, I declare the nominations closed and Mr. Hardeman Chair. Come on up.

ELECTION OF VICE-CHAIR

The Chair (Mr. Ernie Hardeman): Thank you very much, and good afternoon. We'll entertain motions to nominate the Vice-Chair.

Mr. Lorenzo Berardinetti: I nominate Ted Chudleigh as Vice-Chair.

The Chair (Mr. Ernie Hardeman): Are there any further nominations? If not, nominations be closed.

Mr. Ted Chudleigh: I will accept.

The Chair (Mr. Ernie Hardeman): Will you accept the nomination? That's what I was supposed to say.

Mr. Ted Chudleigh: I will accept the nomination.

The Chair (Mr. Ernie Hardeman): Thank you very much. Mr. Chudleigh is elected Vice-Chair of the committee.

APPOINTMENT OF SUBCOMMITTEE

The Chair (Mr. Ernie Hardeman): We have another motion: to appoint a subcommittee. Ms. Jaczek.

Ms. Helena Jaczek: I move that a subcommittee on committee business be appointed to meet from time to time at the call of the Chair or at the request of any member thereof, to consider and report to the committee on the business of the committee;

That the presence of all members of the subcommittee is necessary to constitute a meeting; and

That the subcommittee be composed of the following members: the Chair as Chair; Mr. Berardinetti, Ms. McKenna and Ms. DiNovo; and

That substitution be permitted on the subcommittee.

The Chair (Mr. Ernie Hardeman): Thank you very much. You've heard the motion. Any further discussion? If not, all those in favour? Opposed, if any? The motion is carried.

That concludes the reason and the purpose of our meeting this afternoon. We look forward to many more meetings. I can assure you that this will likely be the most expedient meeting that we will have over the course of events.

Again, I want to thank everyone for allowing me to chair it once again. We look forward to accomplishing great things. So, thank you very much. We'll call this meeting adjourned.

The committee adjourned at 1408.

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STANDING COMMITTEE ON SOCIAL POLICY

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Monday 15 April 2013



Journal des débats (Hansard)

Lundi 15 avril 2013

Standing Committee on Social Policy

Committee business

Comité permanent de la politique sociale

Travaux du comité

Chair: Ernie Hardeman
Clerk: William Short

Président : Ernie Hardeman
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STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 15 April 2013

Lundi 15 avril 2013

The committee met at 1407 in committee room 1.

COMMITTEE BUSINESS

The Chair (Mr. Ernie Hardeman): I call the social policy committee to order. We are here today to deal with a motion that was sent to the committee under section 111 of the standing orders. With that, we have a motion here by Jane McKenna, MPP for Burlington. Ms. McKenna.

Mrs. Jane McKenna: Thank you, Chair. I move that, pursuant to standing order 111(a), the Standing Committee on Social Policy immediately initiate a study and investigation regarding recent reports where diluted chemotherapy drugs were administered to patients in Ontario, and whether or not the Ministry of Health and Long-Term Care effectively exercised its role into the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

That the committee shall be able to call witnesses under oath as it sees fit to assist in the committee's investigation and shall produce a report that includes, but is not limited to:

- investigating the apparent lack of oversight, lack of standards and/or absent monitoring for companies like Marchese Hospital Solutions, by the Minister of Health and Ministry of Health and Long-Term Care;

- assessing the adequacy of the Ministry of Health's pharmaceutical regulatory regime, guidelines and drug inspection procedures and protocols;

- any impact on the nearly 1,200 cancer patients in Ontario who received a flawed or diluted drug during their cancer treatments;

- whether the steps taken by the government and/or the ministry and/or the minister were adequate in responding to this matter;

- what international best practices could have and should have been used to ensure proper checks and balances were and are put in place for companies that produce complex drugs and the hospitals that use those drugs so as to prevent a situation like this from ever happening again.

Notwithstanding the committee's meeting schedule as ordered by the House, the committee shall seek permission from the House leaders and of the House to be permitted to sit at the call of the Chair and to meet notwithstanding prorogation.

The Chair (Mr. Ernie Hardeman): Very good. You've heard the motion. Debate?

Mrs. Jane McKenna: Yes. This does not need to be a partisan issue. Patients deserve answers and immediate action, and we owe it to these families and to these patients to do the best we possibly can to get to the bottom of all that's gone on so far.

The Chair (Mr. Ernie Hardeman): Further debate?

M^{me} France Gélinas: I would say that I certainly agree with the spirit of this motion, to give this House an opportunity to report to Ontarians as to: How come it went so wrong? How come it went so wrong for such a long time? Ontarians deserve answers, and I think if we can help some people get those answers, help them turn the page, help them rebuild their trust in our health care system, then this will have been a very worthwhile endeavour. I intend to file an amendment to the motion.

The Chair (Mr. Ernie Hardeman): Very good, thank you. Ms. Jaczek.

Ms. Helena Jaczek: We also, obviously, are very concerned about what we have learned about the situation with Marchese Hospital Solutions. Just to question Ms. McKenna a little bit in terms of her first bullet point: You reference the Minister of Health and Ministry of Health and Long-Term Care. I'm assuming that you mean the Ontario Minister of Health, because we will be bringing an amendment also, an addition to what you have proposed, that will involve the federal government as well. We feel that Health Canada clearly has oversight over manufacturing of pharmaceuticals, and therefore, we will bringing, in other words, a little bit of an expansion to the terms of reference here. I just wanted to clarify that you didn't mean the federal—

Mrs. Jane McKenna: Yes.

Ms. Helena Jaczek: Okay. So in fact it should be the Minister of Health and Long-Term Care and the ministry.

The Chair (Mr. Ernie Hardeman): Okay, thank you. Did you want to answer the question about whether it means the Ontario Minister of Health? I would presume so.

Mrs. Christine Elliott: Yes, the motion, as written, does reference the Ontario Minister of Health and Ministry of Health and Long-Term Care.

We have brought this forward because of the significant public concern around this issue. Over 1,200 patients have been affected by it, and I think that people across Ontario who have received a cancer diagnosis and

are undergoing chemotherapy treatment now, generally speaking, have a concern about this. So we believe that it is our responsibility as legislators to hold hearings as quickly as possible. Time is of the essence of course when you do have a cancer diagnosis, so we believe that the mechanisms that can be brought forward through this committee will allow for a timely and thorough investigation.

The Chair (Mr. Ernie Hardeman): For clarification, I would point out that the—what shall we say?—guidelines for the committee are, in fact, to look into matters of provincial jurisdiction. So if the committee deems in other factors that may be involved during the process of your deliberations, if you wish to look beyond the Ontario Minister of Health, you would have the ability to do that, but the resolution would not be appropriate to reference another Minister of Health other than the provincial Minister of Health.

Ms. Helena Jaczek: It would be simply, obviously, to potentially call witnesses and investigate the roles of other jurisdictions beyond the provincial ministry.

The Chair (Mr. Ernie Hardeman): Yes, that would be true. Yes, Ms. DiNovo?

Ms. Cheri DiNovo: This is an amendment; our health critic, France, will move that amendment. But I just wanted to raise a concern that some folks in the New Democratic Party had. I know that this committee cannot compel anyone to testify—only the House can do that—but just to ask for sensitivity where calling victims is concerned. We would hate to see victims called; I just wanted to put that on record.

The Chair (Mr. Ernie Hardeman): Has everybody got their first word in? Ms. Gélinas, you have an amendment?

M^{me} France Gélinas: I'm hoping mine will be sort of a friendly amendment, as it only deals with adding a few words.

The Chair (Mr. Ernie Hardeman): Okay, just hold it for a minute. We are distributing your copies so everyone will have it.

Carry on.

M^{me} France Gélinas: Basically, if you look at the motion the way the member from Burlington has read it into the record, there's a series of points. My amendment would be to the second bullet point, which starts with "assessing the adequacy of the Ministry of Health's"—we all know where we are? Okay. I would add to this, basically, "assessing the adequacy of the Ministry of Health's outsourcing strategy, pharmaceutical regulatory regime, and guidelines and drug inspection procedures and protocols;"

So within this, we would look at outsourcing, as we all know by now that those drugs used to be mixed in the hospital. A decision was made to outsource those two chemotherapy drugs—so just to make it clear that we also look at this.

I don't know if it's considered a friendly amendment or if we have to vote, but I'm open to any or both.

The Chair (Mr. Ernie Hardeman): Okay. Debate on the amendment? Yes?

Ms. Helena Jaczek: I'm sure the government will have no difficulty whatsoever in including the words "outsourcing strategy" to that second bullet.

The Chair (Mr. Ernie Hardeman): Okay. Further debate?

Mrs. Christine Elliott: We don't have any problem with the amendment either. I think that it is very helpful.

The Chair (Mr. Ernie Hardeman): Okay. With that, if there's no further debate on the amendment, we'd call the vote on the amendment. All those in favour of the amendment? Opposed? The motion is carried.

Back to the main motion, as amended. Further debate?

Ms. Helena Jaczek: So, if I may move an amendment, which is in essence an addition, as a second bullet what we would like to have—and we feel that this would really improve the full scope of what we're looking at and be extremely helpful to getting to some answers on this very sad situation. So what we want to add is, and I will move that the motion be amended to include, the following: "investigating the roles, respectively, of the Ministry of Health and Long-Term Care, the Ontario College of Pharmacists, Health Canada, and any other organizations the committee might identify in overseeing, providing standards for, and monitoring companies like Marchese Hospital Solutions." In other words, we want to get a full picture of any regulatory regime that might be out there. I would like a recorded vote for that amendment, please, Mr. Chair.

The Chair (Mr. Ernie Hardeman): Okay. You've heard the motion. Discussion?

M^{me} France Gélinas: I think your amendment is very much in line as to what we are trying to do; it just spells it out more. I have no problem supporting such an amendment. It's going in the direction that we need to go.

The Chair (Mr. Ernie Hardeman): Any further debate on the amendment? Yes, Ms. Elliott?

Mrs. Christine Elliott: We would agree that it does clarify. There is going to be an issue, no question, of jurisdictional issues, so we would agree with this amendment.

The Chair (Mr. Ernie Hardeman): Okay. Any further debate on the amendment? If not, the recorded vote has been requested. So we'll call the vote.

Ayes

Berardinetti, DiNovo, Elliott, Gélinas, Jaczek, Mangat, McKenna, McNeely.

The Chair (Mr. Ernie Hardeman): The motion is carried.

Further debate on the motion, as amended? No further debate? We'll call the vote on the main motion, as amended. All those in favour? Opposed? The motion is carried.

The Clerk of the Committee (Mr. William Short): As amended.

The Chair (Mr. Ernie Hardeman): The motion is carried, as amended. I think that was obvious. That was the vote I called. You only have to say it so many times.

Yes, Ms. Gélinas?

M^{me} France Gélinas: Chair, I want to be absolutely certain that as we start this process we're all on the right page. There are over a thousand families right now that have lived through a really difficult couple of days, really difficult news, and they still have to deal with it—probably for many days, weeks and months to come. I know that it is within our power to compel witnesses to come—

Ms. Cheri DiNovo: No, we can't.

M^{me} France Gélinas: —and testify—

Ms. Cheri DiNovo: Not at this committee level.

M^{me} France Gélinas: Okay. Apparently, it's not within our power to compel witnesses. I would ask for the different parties' understanding that we could do a lot of harm to a lot of people and families by asking people directly affected to come and testify. I would encourage my colleagues on this committee to really think long and hard when you select the list of witnesses that you want to come and testify, when you look at this, to really try to protect people who have suffered enough. We could not protect the care that they were getting; we can at least respect them and protect their dignity. That means not calling them to this committee. I want to make absolutely sure that the members that we will be working with from the three parties understand where we stand.

The Chair (Mr. Ernie Hardeman): I appreciate the comment very well. I think that would be universal on the committee.

I would just point out that the committee does not have the power to demand that anyone come. Only the House has that power, and the committee would have to request it to do it. If that should happen, there would be an opportunity as a committee to oppose that request, to not let that happen.

Having said that, I think we would all be very cautious. As you pick what we need to know as to what went wrong, I think it's reasonable to assume that none of what went wrong was the patients' fault. I think the people who were impacted by this would not and should not be considered as part of a group that should be invited to see whether we can get to the bottom of this. It's how it happened, not who it happened to, that I hope the committee will be looking at.

Hopefully, we do respect those people with enough consideration that we would not infer in any way that

they had to be part of this process if they deemed that they would rather not. At the same time, I don't want to eliminate them, to suggest that their position is not important in what we're doing here.

Ms. Helena Jaczek: The government would have no intention of calling anyone—a patient—that might have been impacted by this. This is not something we would do.

The Chair (Mr. Ernie Hardeman): Okay. Does that cover it?

M^{me} France Gélinas: I take it we will have a subcommittee at some point that will decide on the list of witnesses, but I want to put on the record that we will be asking the Ombudsman to come and appear before our committee.

The Chair (Mr. Ernie Hardeman): I think that's the next order of business, if that's where we're going. The committee has a choice then. They have the ability as a full committee to start that process today, as to how you want to proceed with this. The normal course of events would be that we agree to appoint a subcommittee to make recommendations as to the type of witness and who you would want and then report back to this committee. I would hope that we could have that subcommittee report reasonably quickly after this meeting, not necessarily now but this week, so we would be ready to deal with that report next Monday when we meet, if that's the wish of the committee. Any comments on that or any questions? You look like you have something, Ms. McKenna.

Mrs. Jane McKenna: I was just going to say as soon as possible, because time is of the essence. So hopefully everybody will be on the same page with that.

The Chair (Mr. Ernie Hardeman): Ms. Gélinas.

M^{me} France Gélinas: If I can be so bold as to say, if we already know who will be on the subcommittee, could we just stick around right after this meeting and meet for the first time?

The Chair (Mr. Ernie Hardeman): I have no problem with that. I think it will be Ms. Elliott and—there we go. We have an agreement. We will meet right after this meeting for our first subcommittee meeting.

You know what they say, any other comments for the good of Rotary? If not, thank you very much for coming out this afternoon. We look forward to moving expeditiously through this process to get answers for the people who are waiting.

The committee stands adjourned.

The committee adjourned at 1423.

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Ms. Jane McKenna (Burlington PC)

Substitutions / Membres remplaçants

Mrs. Christine Elliott (Whitby–Oshawa PC)

M^{me} France Gélinas (Nickel Belt ND)

Mr. Phil McNeely (Ottawa–Orléans L)

Also taking part / Autres participants et participantes

Mr. Ted Chudleigh (Halton PC)

Mr. Michael Mantha (Algoma–Manitoulin ND)

Clerk / Greffier

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Mardi 16 avril 2013

Standing Committee on Social Policy

Subcommittee report

Oversight of pharmaceutical
companies

Comité permanent de la politique sociale

Rapport du sous-comité

La surveillance, le contrôle et la
réglementation des entreprises
pharmaceutiques



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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Tuesday 16 April 2013

Mardi 16 avril 2013

The committee met at 1600 in committee room 1.

The Chair (Mr. Ernie Hardeman): I call the committee on social policy to order. We are today starting the first day of drilling into the study related to recent reports where diluted chemotherapy drugs were administered to patients in Ontario, and whether or not the Ministry of Health and Long-Term Care effectively exercised its role into the oversight, monitoring and regulation of non-accredited pharmaceutical companies. That's the purpose of our committee as we move forward.

SUBCOMMITTEE REPORT

The Chair (Mr. Ernie Hardeman): The first item of business that we must deal with is to welcome our guests, but we do have to do a little business first. We have to have the report from the subcommittee to the committee to structure today's meeting. Ms. Elliott.

Mrs. Christine Elliott: I'm pleased to read the subcommittee report.

Your subcommittee met on Monday, April 15, 2013, to consider the method of proceeding on the standing order 111(a) study and investigation regarding recent reports where diluted chemotherapy drugs were administered to patients in Ontario; and, whether the Ministry of Health and Long-Term Care effectively exercised its role into the oversight, monitoring and regulating of non-accredited pharmaceutical companies, and recommends the following:

(1) That the Clerk of the Committee schedule the Ministry of Health and Long-Term Care for one hour and 30 minutes on Tuesday, April 16, 2013. That the time allotted for the ministry briefing be 30 minutes and the remaining hour be evenly split by the three political parties.

(2) That each party provides the committee Clerk with a list of potential witnesses by noon on Thursday, April 18, 2013.

(3) That witnesses be scheduled in one-hour-and-20-minute intervals.

(4) That witnesses be offered up to 20 minutes for their opening remarks, and the remaining hour be used by each political party for questioning on a rotating basis.

(5) That the committee Clerk, in consultation with the Chair, be authorized prior to the adoption of the report of the subcommittee to commence making any preliminary arrangements necessary to facilitate the committee's proceedings.

The Chair (Mr. Ernie Hardeman): You've heard the motion. Any discussion? If not, I'll call the vote. All those in favour? Opposed? The motion is carried.

OVERSIGHT OF PHARMACEUTICAL
COMPANIESMINISTRY OF HEALTH
AND LONG-TERM CARE

The Chair (Mr. Ernie Hardeman): The next item on the agenda, of course, is to have a deputation from the Ministry of Health and Long-Term Care. As our guests at the table will know, as they just listened to the subcommittee report, number 1 was to call the Ministry of Health and Long-Term Care to make a presentation, to give us an overview as we start the meeting.

The second item, of course, on the list was that each party provides the committee Clerk with a list of potential witnesses by noon on Thursday, April 18, 2013. The reason I mention that, of course, is that I wouldn't be surprised that some of the people who are here helping us, giving an overview, may very well be in the list to be called back as witnesses in the future. I just put that out there, to make sure we understand, as we're going through, that that may very well happen. There seems to be a broader representation here today than how maybe just the overview was envisioned. We're happy to have you here, but we just want to leave it with that.

With that, I'll turn it over to the Clerk to start appropriately with the affirming or the swearing of the oaths.

The Clerk of the Committee (Mr. William Short): Mr. Rafi, we'll start with you. You prefer to swear an affirmation?

Mr. Saād Rafi: Yes, I do. Affirmation.

The Clerk of the Committee (Mr. William Short): If you could just raise your right hand, please.

Mr. Rafi, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Saād Rafi: I affirm that, yes.

The Clerk of the Committee (Mr. William Short): Thank you. Ms. Brown, affirmation as well?

Ms. Catherine Brown: Yes.

The Clerk of the Committee (Mr. William Short): Ms. Brown, do you solemnly affirm that the evidence

you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Catherine Brown: Yes, I affirm.

The Clerk of the Committee (Mr. William Short): Thank you. Mr. Sherar, did you want to swear an oath?

Mr. Michael Sherar: Yes.

The Clerk of the Committee (Mr. William Short): The Bible is there. Mr. Sherar, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Michael Sherar: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Mr. Moleschi, did you want to swear an oath as well?

Mr. Marshall Moleschi: Yes.

The Clerk of the Committee (Mr. William Short): Mr. Moleschi, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Marshall Moleschi: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you all very much for being here. Again, going back to the subcommittee report, as it pointed out, we have allotted half an hour for the presentation for the deputants to speak about what they wish to tell us. Then we'll have 20 minutes for each party to ask any questions they may have. We would ask that as you start your presentation you give your name, for the record, to the speaker system so it can be put into Hansard. With that, we'll turn the meeting over to you to make your presentation. Deputy, we'll let you—

Mr. Saäd Rafi: Thank you very much. Saäd Rafi. Good afternoon. I'd like to thank you for the opportunity for us to provide you with a briefing on this matter.

As I mentioned, my name is Saäd Rafi. I am the Deputy Minister of Health and Long-Term Care. Joining me this afternoon, on my right, from the ministry is Catherine Brown, who is an assistant deputy minister. On my immediate left in addition, from Cancer Care Ontario, is the CEO, Michael Sherar. To his left, from the Ontario College of Pharmacists, is the registrar, Marshall Moleschi.

We will be providing details about the chronology of events as information about what happened began to surface and the various steps that were taken along the way. Before we do that, though, let me first express our concern for the many patients and their families who have been affected by this incident. At the best of times, dealing with cancer and chemotherapy is a very stressful and difficult experience.

Our task in uncovering what happened is complicated somewhat by the complex nature of our health care system, which operates on a number of levels and, in this

case, involves several different players, but we are determined to find all those facts.

Let me tell you more about who is involved and who is committed to working with the province to find out what happened so that it does not happen again.

Cancer Care Ontario is charged with steering and coordinating this province's cancer services and prevention efforts. Cancer Care Ontario leads systems planning, establishes guidelines and standards, and tracks performance targets to ensure system-wide improvements in cancer care.

The Ontario College of Pharmacists is the regulatory body for the practice of pharmacy in Ontario. It's important to know that no person may establish or operate a pharmacy in Ontario unless a certificate of accreditation has been issued by the college for the pharmacy. The college is here today and they will take you through their role in the system as a regulator and outline the work they have undertaken to investigate this incident.

Public hospitals also have a key role in caring for patients and, in that role, administering treatment, including pharmaceutical products. Ontario hospitals are not-for-profit, community-based corporations that are approved by the Ministry of Health and Long-Term Care under the Public Hospitals Act.

Among our many responsibilities at the Ministry of Health and Long-Term Care, we develop legislation, regulations, standards, policies and directives for Ontario's health care system.

Another key partner in the Ontario health care system is Health Canada, the federal body responsible for considerable oversight, including those who manufacture and prepare pharmaceuticals in non-pharmacy settings.

We all have an important role to play in ensuring quality of care and safety for patients.

We know that on April 2, Cancer Care Ontario publicly reported that a number of patients at four Ontario hospitals who underwent chemotherapy treatment within the last year received lower-than-intended doses of two cancer drugs, cyclophosphamide and gemcitabine. We don't yet know what specific effect this diluted treatment might have had, but the fact that this situation came about is unacceptable. We need to understand all of the information about how this happened so that we can ensure it does not happen again.

We know that the four Ontario hospitals—London Health Sciences Centre, Windsor Regional, Lakeridge Health and Peterborough Regional Health Centre—immediately stopped using the under-dosed chemotherapy drugs and took the necessary precautions to ensure proper doses of the drugs were administered.

All affected patients and/or their families have been notified by the hospitals and have either met with their oncologist or have made arrangements to do so. Mr. Sherar, from Cancer Care Ontario, will provide more information about the steps that have been taken to notify and meet with patients.

As you know, on April 9, the government selected Dr. Jake Thiessen, the founding director of the University of

Waterloo's School of Pharmacy, to conduct an independent review of the province's cancer drug supply chain. His review will focus on the under-dosing of chemotherapy drugs at the four hospitals here and also one in New Brunswick. His job is to find out how it happened and why, and then to provide recommendations on how to prevent it happening again.

To support Dr. Thiessen's review and co-ordinate the response to this incident, we have convened a working group with representation from the affected hospitals, the Ontario Hospital Association, Cancer Care Ontario, the Ontario College of Pharmacists, the province of New Brunswick, Health Canada and others, as necessary.

We have discovered that there are clear limitations on what the Ontario College of Pharmacists can do in ensuring the safety of these drugs. As I mentioned earlier, they can inspect pharmacies and regulate members of the college, but not manufacturers.

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We don't know how these manufacturers or this company, which prepares products, fell through a gap, but we need to learn how and why, and jurisdictions like the provinces and the federal government need to continue to work together so we can make sure there is no gap in oversight in the future. Dr. Thiessen and the working group will help find the answers, and the various organizations involved in the delivery of cancer drugs will come together to act on those answers.

As I mentioned at the outset, two of these organizations, Cancer Care Ontario and the Ontario College of Pharmacists, are here today and will provide their perspective on that situation. After that, we will be pleased to answer your questions, so I'll immediately turn it over to Michael Sherar, and then Marshall Moleschi will follow. Thank you.

Mr. Michael Sherar: Thank you, Saäd. If it's the pleasure of the Chair, I'll continue. Again, at the pleasure of the committee, what I had proposed to do was just give a brief background on myself, the role of Cancer Care Ontario generally with respect to chemotherapy, and then I'll talk about chemotherapy safety and then go on to a chronology of events that occurred subsequent to the discovery of this error, if it pleases the committee.

Just briefly: I am the president and CEO of Cancer Care Ontario. I'm a medical physicist and research scientist by professional background. I've actually worked in the Ontario cancer system since 1985, when I started my PhD. From 2006 until 2011, I was CCO's vice-president for planning and regional programs and had the responsibility of developing regional cancer programs, including capital planning for cancer services across the province.

Prior to my role as CCO's vice-president, I was in fact regional vice-president for cancer services in London for Cancer Care Ontario and vice-president of the London regional cancer program at London Health Sciences Centre.

At the start of my comments, I just want to echo Saäd's comments with respect to our concern for patients

and their families impacted, and as you'll see in my comments in the chronology of the events, of course that was our first priority in working with hospitals around notification and support of patients who were affected by this error.

Before I get into the chronology of events, I thought it may be worthwhile for the committee just to talk a little bit about the role of Cancer Care Ontario and who we are. We are an operational service agency of the Ministry of Health and Long-Term Care and we're governed by the Cancer Act. Our board of directors is appointed by the Lieutenant Governor in Council, and we have accountability to the Ministry of Health and Long-Term Care, primarily through a memorandum of understanding; the current one is dated 2009. This includes a number of responsibilities, including a protocol with respect to information exchange, communication and issues management. We're also accountable to the government through a series of Management Board of Cabinet directives.

With respect to the cancer system, we are the Ontario government's chief adviser on cancer control services and the system through which those services are provided. Our mandate is to drive quality and continuous improvement in disease prevention, screening, the delivery of care, and patient experience for cancer. As you may be aware, we're doing additional work now in the area of chronic kidney disease in the province.

We don't operate or manage the hospitals that provide cancer control services, but we do have funding agreements, now in excess of over \$800 million, with those hospitals and other cancer care providers which link that funding to a framework of accountability, delivery of data and continuous quality improvement in the system as a whole. We do that primarily through the development and implementation—we do this with partners across the province—of a multi-year Ontario cancer plan. The way in which we work is through a series of regional networks, each led by a regional vice-president for cancer in each of the 14 local health integration networks.

With respect to systemic treatment, or chemotherapy—this is the modality of treatment that uses drugs to slow or stop cancer cells from multiplying or spreading—again, we work with the Ministry of Health and Long-Term Care, our regional cancer programs and health care providers on the organization and delivery of chemotherapy across the province. Through that, we're responsible for developing and implementing an agenda of quality improvement for systemic therapy, and that leverage is on regional cancer programs and our partnerships with clinical networks throughout the province. That includes monitoring and facilitating access to treatment and enhancing the quality and efficiency of systemic treatment, including development of evidence-based guidelines, and that's through our program in evidence-based care. We develop organizational standards and performance measures, and we coordinate and share information with health care providers and hospital administrators across the province to continually improve

the design and delivery of our systemic treatment system in the province.

As it relates to chemotherapy safety, we have produced several guidelines focused on safety issues for chemotherapy; as examples, in August 2009, we issued key components of chemotherapy labelling, so these guidelines focused on what are the necessary components and formatting of chemotherapy labels to maximize safe delivery and minimize errors. Those guidelines—and this is the way in which we work with our providers across the province—are supported by education programs concordant to those guidelines, and we measure concordance with those guidelines across the province. It's important to note that these guidelines are directed at hospital pharmacies, not compounding companies.

Earlier to these guidelines, we have issued guidelines for regional models of the care for systemic treatment standards for organizations that provide the delivery of systemic treatment across the province and also safe handling from the perspective of providers of chemotherapy within those organizations.

That's just a summary of some of the work that we do generally with respect to chemotherapy, and specifically with respect to chemotherapy safety.

What I would like to do now is just to go on to a chronology of the events subsequent to the discovery of this error. I'll start when Cancer Care Ontario was first notified of the issue, which was on Wednesday, March 27, and this came through email and subsequent telephone discussion, actually from Neil Johnson, who's the regional vice-president in London and for the southwest region. At that time, in discussion with Neil, it was decided, following this outreach and understanding the work that had already gone on between hospitals, to convene a conference call with what we knew then were the affected hospitals—and at that time, we knew it was Windsor, Lakeridge and London—and organized a call the next day, in the afternoon. That was to give time for the hospitals to have their own incident management meetings earlier.

So we held that conference call the next day on March 28. In accordance with our protocol for notifying the Ministry of Health, we did also the next day—it was around 2 p.m.—notify the Ministry of Health with respect to the issue and what we knew at the time about the issue, and that was through the communications and information branch at the ministry.

We had the conference call with the affected hospitals, and they included not only the regional vice-president but leaders within the cancer program—pharmacy staff, oncology leads and communication leads—so that we could, together with Cancer Care Ontario and the hospitals, get a fuller understanding about the issue and establish appropriate next steps that we might be able to coordinate across the hospitals.

It was during that call that we really learned the early perspectives on the nature of the error and the approximate number of patients that were affected, and each of the hospitals undertook to disclose their plans with

respect to notifying patients. We also learned that there was another jurisdiction that was impacted, and that was, of course, Horizon Health Network in New Brunswick. The focus of the call, though, was primarily on the patient notification plans at the hospitals.

We worked with the hospitals on that call and understood that—of course, as you'll know—there were quite different numbers of patients affected at the different hospitals. The largest number was in London, and they had the biggest task of assembling all of the information and getting the plans ready so that they could notify patients. They were looking to a little later date than the other hospitals to start notification of patients, and I'll talk a little bit about the subsequent actions with respect to that.

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We did at the time want to immediately understand whether there was any issue in the other hospitals that deliver chemotherapy in the province—there are 77 of them—so we undertook to develop quickly an issues briefing note that we would be able to provide through our network of regional vice-presidents to those 77 treatment hospitals.

I would say that across Good Friday and Saturday of the Easter weekend, all of the parties worked to develop that comprehensive issues briefing that we could rapidly get out to other hospitals to ensure that what we thought was known about the hospitals affected—just those hospitals—that there weren't other hospitals affected.

In addition, on March 30, CCO was contacted by LHIN CEOs and hospital CEOs from the regions affected, with a request that we hold a meeting to update them on the issue—and their desire to brief the minister directly. We recommended at that time that we would hold a joint call with all the LHIN CEOs from the regions affected, and the hospital CEOs, on Easter Monday, so that was scheduled.

On Easter Sunday, we did provide another issues briefing notice to the Ministry of Health through the communications and information branch, again summarizing all the knowledge that we had gathered to date at that point.

It was that afternoon, on the Easter Sunday, that we contacted all of the regional vice-presidents in the cancer programs, calling their attention to the issue and asking them, with a briefing note, to confirm that this specific issue didn't involve any other systemic treatment hospitals within their regions, so that we could cover the entire province. The issues briefing note that was completed was shared with all of the regions at that time.

We continued to work with the specific hospitals affected on the plans for notification. We understood at that point that Windsor was more ready to start their activities with respect to patient notification and—legitimately, I think—was eager to start that as soon as possible.

We did understand that London, because of the larger volume of patients, was not quite ready. So we agreed, after a call that we had on the Sunday, that we would

defer that decision together until the Monday call that I was going to have with the LHIN CEOs and the hospital CEOs together.

We did, on that call, look at the issues around patient notification and agree together that Windsor would start the next day, on the Tuesday. We understood that London was working as hard as they possibly could to be ready to start their patient notification and had indicated that they likely would be ready by Wednesday evening or Thursday, but we agreed together that we would do this in a staggered way. It was going to take some time to notify all patients anyway. Windsor indicated to us that because some of the patients were in active treatment, they had a duty to notify patients when they were coming in for appointments that were actually scheduled on that Monday. So the notification, I think, actually started on the Monday and then continued through the rest of the week. It was the next day that we issued the press release.

I'm almost finished.

With respect to the press release, I think, since then our work has been working with hospitals to help them in terms of their own patient notification efforts, getting feedback from hospitals across the province that this wasn't an issue in any other hospital with respect to this specific error. But we also checked with them with respect to the general issue, what we knew about the nature of the error, that they were checking with respect to all of our guidelines and the issues of preparation of chemotherapy drugs following those guidelines and checking with their pharmacy staff. We have got check-back from all of the hospitals both on the specific issue and the general issue of preparation of chemotherapy, that they have checked and double-checked those processes.

That work is now complete, and we're now in the process of supporting the work of Dr. Thiessen, of course, who's leading the third party review, and happy to work with all of the organizations involved in supporting that work, to really understand what happened with respect to this error and what we can learn in terms of improving the system for the future.

The Chair (Mr. Ernie Hardeman): Thank you very much.

Mr. Marshall Moleschi: Thank you, Michael. My name is Marshall Moleschi. I'm the registrar at the Ontario College of Pharmacists.

A little bit about my background: I have been a community pharmacist a long time ago, a hospital pharmacist—I did have some experience in cancer chemotherapy—a hospital administrator, and I have a little bit of experience in introducing a northern British Columbia cancer centre. I've been registrar in the province of British Columbia for the college of pharmacists and I have been registrar here in Ontario for about the past year and a half.

My political experience goes back to the last century as a pharmacist, so it's been some time ago.

A little bit about the college of pharmacists: We're the regulatory body for profession of pharmacy in Ontario.

Our mandate is public protection with regard to the conduct of pharmacy health care professionals and the operation of community pharmacies. The college receives its authority from a variety of laws, including the Pharmacy Act, the Regulated Health Professions Act and the Drug and Pharmacies Regulation Act.

To be a pharmacist or a pharmacy technician in Ontario you need to be registered with us, with the college, and to operate a community pharmacy in Ontario you need to be accredited by the college.

Section 118 of the DPRA, or the Drug and Pharmacies Regulation Act, specifies that the college does not have jurisdiction over "drugs compounded, dispensed or supplied in and by a hospital." Therefore, until now the college has not been focused on the hospital drug distribution system.

With respect to community pharmacies, we set and maintain accreditation standards. We inspect pharmacies before they first open and soon after opening to ensure that they meet our standards. We also conduct routine inspections every three to five years approximately, and we will also do it more often if it's warranted or if they're engaged in something that we think is a little bit more risky type of an activity.

Several years ago, we introduced the point-of-care symbol, which is displayed in all registered community pharmacies to provide some assurance to the public or to provide the assurance to the public that they've successfully passed the accreditation process.

With respect to our practitioners, we set and maintain entry-to-practice standards to ensure they have the knowledge and skills when entering practice. We have a quality assurance program which requires practitioners to demonstrate on an ongoing basis their competency throughout their career. We hold practitioners accountable to practise within their scope of practice, to all relevant regulations, standards of practice and ethical conduct. We provide guidelines and policies to practitioners to support them in their practice as they go about the scope of their practice and upholding the standards of practice.

Should there be any concerns about their practice, we have a complaints inquiry and discipline process, so any member of the public can file a written complaint with the college and I, as registrar, can initiate an investigation. All complaints that are received are investigated in a timely manner and their priority is based on their risk of harm to the public. Notice and findings of our discipline cases are made public.

The public trust and confidence is maintained through our public register, which lists all pharmacists and technicians currently in good standing. That can be found on our website. Any notations regarding disciplinary actions are also noted there. The college website also provides a list of all community pharmacies in good standing with this accreditation.

I'd like to go to the facts regarding this current situation. We take matters such as this—

The Chair (Mr. Ernie Hardeman): Just wrap up in a couple of minutes.

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Mr. Marshall Moleschi: A couple of minutes, yes—extremely seriously. We're committed to our mandate of public protection. I'll give you a brief overview of what has transpired.

March 31: The college first became aware of the issue of underdosing of chemotherapy medications when I received a phone call at Easter dinner while I was on vacation in Vancouver. I immediately notified my senior staff, and I returned to Toronto the following day. I confirmed that appropriate steps were taking place to ensure public safety—so there's withdrawal of product, that sort of thing that has just been talked about. We contacted Health Canada to establish a plan to jointly and immediately look into the situation. The college has a long and positive relationship of collaboration with Health Canada in dealing with these types of issues, and that continues.

The college, on April 3, appointed an investigator with two Health Canada inspectors, and we visited the premises. From April 3 to the present, we have had an ongoing investigation into this matter. We're continuing to work in partnership with Health Canada, and we do have stages to our investigation. If there are any questions, I can explain what that is.

In addition to our specific investigation, the college is actively a member of the ministry's working group and will provide support to Dr. Jake Thiessen's independent review of the quality assurance in this province around the cancer drug supply chain. We're continuing to work closely with the ministry to identify opportunities to make enhancements to our jurisdiction to provide the authority and oversight of facilities such as this that may fall outside our community pharmacy practice.

I just wanted to state that there has been excellent cooperation from all parties involved.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. That does conclude the obligation on you to present yourself. With that, we'll start the questions. We'll start with the official opposition. Ms. Elliott.

Mrs. Christine Elliott: Thank you very much for your presentations. I think at this point, we'll have some fairly general questions, but we may ask—well, I'm sure we will ask you to come back to speak more specifically about what has been going on.

Mr. Moleschi, you indicated that the matter is under active investigation right now within the college. Can you give us more particulars about what's going on with your investigation, separate and apart from the investigation that's going on through the ministry?

Mr. Marshall Moleschi: Our investigation is very specific to the situation. We have identified some pharmacists to people. It's a registrar's investigation; I've initiated a registrar's investigation. We have asked them some questions. They have a period of time, 14 days, to reply. We will then review the responses that take place.

I must emphasize that we're really early in this investigation. We gather that information. We also may

come back to those people who we have identified and ask further questions. We go to other people who we think are involved in this investigation, and then we produce an investigation report, which goes to a committee. That report will go to an internal committee that looks at disposition of that matter. The disposition could be a possibility of three things: Those people could be referred to discipline, they could go to a caution, or the committee may find that there's no further action to take place. That's the way the process would work.

Mrs. Christine Elliott: I'm sorry, could you just give us some guidelines as to the time that you're looking at? You've mentioned something about 14 days. I'm just a little bit confused about when you expect that this report will be ready.

Mr. Marshall Moleschi: It will take some time. The normal process would take in the period of a few months to be able to complete. There are some timelines that are laid out in the act, and we follow the timelines that are consistent with other health care professions. That's the time frame that we're working to. But we're continuing to gather questions and investigate. With Health Canada, we've added some more questions. It's a joint investigation, and we'll probably, within a very short period of time, also go in with Health Canada to ask some more questions and visit the site.

Mrs. Christine Elliott: So this is a registrar's investigation that you've initiated, but you're working with Health Canada on it. Can you give us a bit more specifics about that relationship and how that will unfold within the course of your investigation?

Mr. Marshall Moleschi: We are dealing with an entity that isn't a pharmacy. It was not compounding direct, specific to patients, on orders from a prescriber, like a physician, and it wasn't registered with us. We do want to investigate to see what relations it had and what it was doing, so that's really important. We need to understand, also, when we go into the investigation—because we deal with compounding; Health Canada generally deals with manufacturing, so they have a role in that—we want to work jointly so that we can make sure that the public is safe and we can investigate. Whichever area the information is going to go, we can use our tools in each organization to be able to investigate this matter fully.

Mrs. Christine Elliott: Okay. So, will they be doing their own separate investigation, or do you have—in terms of how it actually operates, could you give us some indication of who will be doing what?

Mr. Marshall Moleschi: We're jointly gathering information. We're gathering information at this stage. If that information leads us down our path—our investigation is going to continue into the conduct of the members who are registrants, the pharmacists involved. When Health Canada finds more information, it can pursue its investigation based on what it has, and its rules and its laws that it has. We are working together in gathering the information, and we'll each use our processes to move that further.

Mrs. Christine Elliott: Would it be fair to say it's more information-sharing, really, at this point that you're doing, rather than a joint investigation?

Mr. Marshall Moleschi: We are using this information to do our investigation. Yes, we are sharing information, but we will use it appropriately to exercise our authorities as we gather that information.

Mr. Saäd Rafi: Can I just supplement that? I don't want to run afoul of the word "investigation," because it may have differing definitions under differing pieces of legislation, but Health Canada is doing a review, asking questions of Marchese, the company that is involved, as they have regulatory and legislative tools to do so, and, we think, some jurisdiction.

You've heard Marshall's responsibilities in his investigation, and the province has asked Dr. Thiessen to take a look at the supply chain. He has been appointed under the Public Hospitals Act, so certainly he can enter hospitals, have that conversation and determine what their role in the handling of product was. He has requested access and to have questions of Marchese, and to this point they have been quite co-operative in doing so. So there are three reviews/investigations.

Mrs. Christine Elliott: Okay, thank you. And you mentioned that your investigation will be coming before an internal committee. Will you be sharing that information with others?

Mr. Marshall Moleschi: We'll need to put it through our processes, and then if it goes to that committee to discipline, then the notice of that discipline is out there and the results of that discipline are published to the public.

Mrs. Christine Elliott: But will the information that you get through the investigation be shared with Cancer Care Ontario, the Ministry of Health or, perhaps, the members of this committee? Is it possible that that information can come forward to us?

Mr. Marshall Moleschi: There are some limitations in legislation, but outside that we would share the information. Without any of those limitations, we would share. I think this committee has the ability to request information.

Mrs. Christine Elliott: Okay, thank you.

If I could, Mr. Sherar: You mentioned the guidelines that you have published on various matters with respect to chemotherapy drugs and the administration of them.

Mr. Michael Sherar: Yes.

Mrs. Christine Elliott: Would you be able to provide the committee with copies of those guidelines?

Mr. Michael Sherar: Yes. They're all public on my website, but we will provide copies of those guidelines.

Mrs. Christine Elliott: All right, thank you.

To Mr. Rafi: Would you be able to provide us with a complete list of all of the members of the team that's taking a look at this, that are working with Mr. Thiessen?

Mr. Saäd Rafi: Yes. We have a working group, and we'll get you the associations and their names.

Mrs. Christine Elliott: Thank you. Those are all my questions. My colleagues may have some.

The Chair (Mr. Ernie Hardeman): Mr. Yurek?

Mr. Jeff Yurek: Sure. Thanks, Chair.

Thanks for coming out. Mr. Sherar, just in addition to supplying the guidelines for cancer care, would you also be able to supply the policy you have in awarding contracts to companies outside the hospital for providing drugs to the hospital?

Mr. Michael Sherar: Maybe Mr. Rafi can speak to this, but we don't have a policy with respect to contracts that hospitals have with suppliers. We don't manage the procurement process for hospitals or have policies around their procurement.

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Mr. Jeff Yurek: Would it be based on each individual hospital, or would it be a Ministry of Health—

Mr. Michael Sherar: That's correct.

Mr. Jeff Yurek: Okay. Are there any other providers in the system providing manufactured or compounded chemotherapy medications to hospitals, or is Marchese the only one?

Mr. Michael Sherar: No, there are others.

Mr. Jeff Yurek: There are others?

Mr. Michael Sherar: There are others, yes.

Mr. Jeff Yurek: Would we be able to get a list of those providers?

Mr. Michael Sherar: I'm not sure. We have a complete list of those providers. We can try to assemble that list as best we know.

Saäd, you might want to speak to that.

Mr. Saäd Rafi: We are trying to find out who's in the industry, because the unregulated aspects—in other words, who are not pharmacies. It's hard to know who else is out there.

But we are trying to work with the Ontario Hospital Association to see who of their members has a supply relationship for cancer drugs. I think that CCO branched out to all hospitals—I believe there are 77 sites that are cancer sites—and asked them who are using various third party suppliers—sorry, who are using Marchese as a third party supplier, and it was narrowed down to these four hospitals. We'll have to go to that next level of questioning, if I understand your question correctly.

Mr. Jeff Yurek: Yes, that would be great. And in regard to the contract with Marchese, who negotiated the contract? Was it the individual hospitals? Was it Cancer Care Ontario? Was it the Ministry of Health?

Mr. Michael Sherar: Again, Saäd, you may want to speak to this. Cancer Care Ontario doesn't negotiate these contracts. Either the hospitals do or there are organizations that work for the hospitals to negotiate these contracts.

Mr. Saäd Rafi: Hospitals are their own duly constituted organizations with a board of directors under the Public Hospitals Act and, I believe, the Ontario Business Corporations Act as well, so they have their own purchasing approach. Some use third party purchasers, outsourcers, to provide all manner of products.

In this world, we are learning that some hospitals receive the material themselves and compound; some

receive compounded material. We don't dictate who they buy from or how they go about procuring, except for the directives and guidelines on procurement that they are obligated to follow, set out by the Ministry of Government Services.

Mr. Jeff Yurek: Can we get a copy of those guidelines from government services, please?

Mr. Saād Rafi: Procurement guidelines? Certainly.

Mr. Jeff Yurek: And in reference to the cancer patients, what is the wait time currently for those patients who have been affected to actually see an oncologist and have a discussion?

Mr. Michael Sherar: As Saād said in his comments, the arrangements for patients to either see their oncologist or schedule an appointment, if they would like, or use some other mechanism to have their questions answered—that process is largely complete with respect to the hospitals' outreach to all of the patients who are affected by this.

Mr. Jeff Yurek: Okay. Marshall, just a quick question, just for clarification: The Ontario College of Pharmacists' investigation on their part of the incident is only focused on the health care professionals who were pharmacists at the time. Is that correct? It's not on Marchese as a whole or the hospitals as a whole? It's just on the health care—

Mr. Marshall Moleschi: The investigations are on the health care professionals who are involved in this, to see if there was any misconduct or any incompetence. That's sort of the investigation that's taking place.

We're also looking because different organizations have the name Marchese in there, so we were looking to see if there was any relationship between Marchese Hospital Solutions, which is a federal corporation, and the relationship with Marchese Health Care pharmacies that are out there as well.

Mr. Jeff Yurek: Okay. So you have no jurisdiction over manufacturing? There's that area between compounding and manufacturing that you—

Mr. Marshall Moleschi: That's correct. Unless it's patient-specific, and that could only be done in a pharmacy—the admixture is not within our jurisdiction right now. We're engaged in conversation with the ministry to see whether our powers can be increased.

Mr. Jeff Yurek: And just one last question. I guess the Ministry of Health would be the question: Is the LHIN involved at all in this whole issue, or situation?

Mr. Saād Rafi: Yes, they have been. I don't know if Michael had a chance to mention that in his chronology, but they were informed early on in the chronology of events. It would be the Erie St. Clair LHIN, so the Windsor area, and then what we call the South West LHIN, which would be the London area—

Interjection.

Mr. Saād Rafi: Oh, and the South East LHIN too—sorry; Central East.

Mr. Michael Sherar: Which covers Lakeridge and Peterborough.

Mr. Jeff Yurek: Thanks. That's all for me now, Chair.

The Chair (Mr. Ernie Hardeman): You have about five minutes left.

Mr. Jeff Yurek: Jane?

Mrs. Jane McKenna: Thank you so much for coming in today. I know we all have the best interests of the cancer patients and their families. My daughter lives in Windsor, and one of her very dear friends is one of these victims in this situation.

When I'm actually listening to Ms. Elliott speak right now, I understand the confusion because it's very difficult. If you knew the questions to ask, we wouldn't be in the position we are in right now. So ultimately, us asking you these questions—we wouldn't be sitting here if we had those questions answered.

I just wonder, how are we going to get a clear plan of what we're actually trying to do? Because it seems that we're not really sure what we're actually putting forward. I guess my question is—for example, you're saying right there that you're going to find out, Marshall, if there's any action to be taken—who hasn't done the proper protocol—but how do you know if they don't know what their job description was? How are you going to know that?

Mr. Marshall Moleschi: So we will be looking at information that we can get from the processes that were in place, so using this tool to be able to find information. We're trying to find out as much information as to the policies and procedures that they have, their job description—all those sorts of things—and gather any relevant information, what their training programs are and that sort of thing.

There are some colleges across Canada that do have some responsibility on the hospital side. British Columbia was one of those. There are standards that you need to look at, and those standards are well laid out. When the college would go in, they would look at the policies and procedures, the training, if they're meeting the modern standards of the day. So those sorts of things are what we would be reviewing.

We're going to try to get that information as well through this mechanism. Even though we don't have that direct responsibility, we're going to use our tools to be able to find that information.

Mrs. Jane McKenna: That's not something that you do on a regular basis right now. We're just doing this because of this situation or—

Mr. Marshall Moleschi: So this college does not have the authority because of an exemption under 118 of an act—

Mrs. Jane McKenna: Right.

Mr. Marshall Moleschi: —to be able to look at the supply. We didn't do that on a regular basis. We have not done that. In the future, the discussions that are taking place right now with the ministry is, is that needed in this province and can we have those sorts of authority? That's part of the discussion that's going on. So we are finding that information.

Mrs. Jane McKenna: So if you don't, who does have the authority?

Mr. Saâd Rafi: If I might. Through the course of this in a very compressed period of time, we've learned that where these drugs were being combined is not considered a pharmacy. So the existing legislative framework that the college has created this gap.

We are working with Health Canada, I would say, hand in glove, because we feel that they have legislative authority, but it's, again, a unique circumstance, how this company has structured itself to combine or prepare these drugs. Health Canada is going through a very rigorous assessment of questions of the company as to how you do your business, and then they're looking at their legislation, how to apply it.

In addition to that, since we have the authority of the Public Hospitals Act, we've asked Dr. Thiessen to come in and say, "Okay. This is a supply chain"—I think to the questions Mr. Yurek was asking—"matter as well, so what happened from a quality assurance point of view on the supply chain?"

We have this working group that meets now on a daily basis, and putting those three components together, we hope to then have that coordinated approach and understanding of the situation as well as the remedies. In some cases, I think it's been well chronicled that there is a bit of a regulatory gap, and that's why we're trying to work with Health Canada to fill it.

Mrs. Jane McKenna: So—

The Chair (Mr. Ernie Hardeman): You're out of time. Thank you very much.

Before we go to the third party, I just want to point out that Mr. Yurek is not a subbed-in member of the committee, and he made a request for a number of documents. So on behalf of Mr. Yurek, I would ask that they be presented.

Interjection: Of course.

The Chair (Mr. Ernie Hardeman): We have to have it officially asked for, so we just wanted to make sure that was done.

With that, we'll go to Ms. Gélinas.

1650

M^{me} France Gélinas: My first question will be for Mr. Moleschi. In the notes that you have given us, on page 4 you talk about, "On April 3, the college appointed an investigator and with two Health Canada inspectors visited the premises." Could you describe which of the premises you visited and does that include premises that are considered a pharmacy and the premises that are presently in the grey zone of not being covered by you because they're not compounding drugs and not being covered by Health Canada because they're not manufacturing? Did you go there?

Mr. Marshall Moleschi: Yes. These two entities are—one is an accredited pharmacy. They occupy a building. It looks like an industrial type of building. There's a pharmacy area available to the public, and we entered that premises with Health Canada and we were looking to ask where the manufacturing was taking place,

so the admixture mixing of the other company. It was not adjacent, but it was close by in the same building, so we were given permission to be able to go into that area and investigate.

M^{me} France Gélinas: Okay. Then that brings me to Deputy Minister Rafi. There is a federal policy document, that I'm sure by now everybody has read and reread, by Health Canada called Policy on Manufacturing and Compounding Drug Products in Canada, and it deals specifically with grey areas. This policy was last updated in 2009, but it dates back to 1997. Do you know what I'm talking about?

Mr. Saâd Rafi: Yes. I've not read the entire policy, but I know what you're talking about.

M^{me} France Gélinas: Okay. Basically, the document lays out a strategy and criteria for determining whether federal or provincial regulators have oversight. It notes that, "discussions may take place between the two jurisdictions for final determination of whether an activity is considered to be compounding or manufacturing." It goes on to note that these decisions are made on a "case-by-case basis."

I take it that the ministry is aware of this policy? We know that there's this grey area. We've living it now, so now we all know, but I'm assuming you knew before I did.

Mr. Saâd Rafi: Well, I don't know when you knew, but we have learned of it recently, yes, certainly in discussions with Health Canada.

M^{me} France Gélinas: Is there someone within the ministry that has responsibility for ensuring compliance with this policy and in making those case-by-case decisions?

Mr. Saâd Rafi: Well, I think that the ultimate answer is yes, because we work—when these situations arise, it's a fairly specific policy that if one doesn't find themselves in this unfortunate circumstance, we may not have been alive to it and its existence.

This is part of our conversation with Health Canada, along with conversations we've had with them on the Food and Drug Act and what we believe to be considerable powers of investigation. As Marshall Moleschi has indicated, they have been, I think, very co-operative in working with us, as has Marchese, the company itself.

M^{me} France Gélinas: Okay. So if we don't look at this particular pharmacy/compounding because I don't know how to call them anymore—

Mr. Saâd Rafi: Yes, exactly.

M^{me} France Gélinas: Can you give me another example where the ministry worked with Health Canada and said, "Okay, we're solid on the pharmacy side. You guys are solid on the compounding side. There's a grey area here. Let's settle it"? Has this happened in Ontario before this case?

Mr. Saâd Rafi: Well, I'm not aware of it, and I'm just saying "recent history." We certainly have worked closely with Health Canada and all other provinces and territories on a particular pharmaceutical-related issue with Sandoz and drug supply, but that was a different

circumstance, but in my three-and-a-little-bit years of tenure in the ministry that's the only example I can recall.

M^{me} France G  linas: Can you reassure this committee that Marchese, being the facility in question, has never made contact with the ministry to let them know, "We have this new corporate structure. Part of our corporate structure is a pharmacy; part of our corporate structure is manufacturing. But we have this corporate structure that falls in between"? Have they ever flagged that to you and informed the ministry of their new corporate structure and what that corporation was doing?

Mr. Sa  d Rafi: I can't answer that right now, but I will get you that answer.

M^{me} France G  linas: Okay.

Mr. Sa  d Rafi: My suspicion is that they did not—what's the word?—proactively come to us and say, "Listen, we've just federally incorporated ourselves"—I think in early 2012—"and we do the following things on the following premises, and this is our corporate structure"—I can't even pronounce the corporate holding company structure; Mezentco or something—"and we have this company underneath that company." I don't think that has happened, but I also don't believe that they have an obligation to do that, just like any other federally incorporated company doesn't have an obligation to come and report in.

M^{me} France G  linas: Okay. And maybe that would be—back to Mr. Moleschi, then. When, through the press, which is where I got most of my information on this—it took quite a bit of time before we realized that we were all calling them a pharmacy. I've been in the system long enough to know that if it's a pharmacy, it falls under your college. I felt pretty confident about it all. Then, almost a week later, we realized that, no, although the hospital was buying from what we thought was a pharmacy, they were actually buying from a federally incorporated corporation that had no oversight. How come it took so long for that piece of it to be discovered?

Mr. Marshall Moleschi: It's the clarity on what they were. We did want to find out what it was that they were doing and under what authority they were doing that. So we did send an investigator in—I think it was the Wednesday; it's in the notes there. We had to get some information. We also wanted to do a company search to understand what that company was. It takes some time, I guess. By Monday, we were confident that they were acting independently and not doing any patient-specific type of compounding, but they were actually doing admixtures. We had to gather that information and then we could announce that it wasn't behaving as a pharmacy, and it was separate from the Marchese Health Care pharmacy. It was Marchese Hospital Solutions that was doing that enterprise. We also wanted to investigate to find out if Marchese Health Care pharmacy was doing any of that as well.

So we did have to do our due diligence, and it did take, I guess, three working days to do that.

M^{me} France G  linas: Okay. Now that it has been found that we have this grey area, I'm sure the field is

talking. Do you figure there are more of those corporate entities in Ontario?

Mr. Marshall Moleschi: To me?

M^{me} France G  linas: To you.

Mr. Marshall Moleschi: We are quite concerned, and we do want to know if there are any areas that may not fall under one jurisdiction or the other. We're very concerned about that. We're working with Health Canada to discover that. What we're talking about here are agencies that have contracted with hospitals, and there are other organizations that are looking into that so that we can get a fairly defined group.

We also want to look at the behaviours of the pharmacies that we're looking at, to make sure that they are compounding patient-specific. There are a number of pharmacies that have compounding listed as some of their activities, and we're reviewing all those records to make sure that they're doing what is appropriate in the legislation. So we're doing our due diligence, and we're reviewing all our records as well.

We're taking efforts to be able to do that, and what we're talking about specifically here is something that is between a group of people so that it can be easily identified by those who are looking at it.

M^{me} France G  linas: Back to you, Deputy: The minister looked quite surprised when she was told—well, she announced to us—that there was this grey area. Was it a surprise to you and your ministry that there was now a corporate structure out there that fell in the grey area of oversight?

1700

Mr. Sa  d Rafi: I think the word "surprise" is less the word for me than, there's frustration and disappointment that it's difficult to pinpoint the problem and then the solution.

My own experience on the economic side of things tells me that companies incorporate and structure themselves in a multitude of different ways for a multitude of different purposes. It's impossible to predict the future by effective regulation or legislation, but we're working very hard to figure out how to close those gaps and, as I mentioned to the earlier question, with Health Canada's support as well, because—I think you've already identified it—there's the combining; there's the manufacturing; what is "preparing"? Is that a Food and Drugs Act issue? Is that an improvement to the regulatory and legislative structure for the college?

M^{me} France G  linas: I guess I spent enough time looking at Ornge's corporate structure to know now that corporations can take very many different forms, none of them for the betterment of the patient. Am I looking at the same thing here? Am I looking at a legitimate health care provider that goes and gets creative with their corporate structure in order to avoid accountability?

Mr. Sa  d Rafi: I can't respond to that. I don't know what motivated them to structure themselves the way they did and to go after business for supplying and combining drugs. That's a question that I think should be put to them.

M^{me} France Gélinas: I will. I just wanted to have your take on it before we go.

I think we got from Mr. Sherar that you will be asking the 77 hospitals that provide chemotherapy treatment if they procure their chemotherapy drugs from—where they're procuring from, if they're not compounding it in-house.

Mr. Michael Sherar: Our questions of the hospitals were specifically aimed at the issues of safety right now with respect to this issue. We had questions initially through our regional vice-presidents around this specific issue of these drug products that we understood from the hospitals had led to the underdosing of patients, making sure that that wasn't an issue in any other hospital across the province. We confirmed that.

We did send out—and this was on April 2—a more general advisory with respect to what we understood about the nature of the issue, the error that had been made and the checking of procedures and policies with respect to guidelines that were in place for the administration of chemotherapy to patients—understanding that issue. They all responded to us, again to our satisfaction, that they had in fact indeed done those checks.

That issue was more around the general nature of preparing chemotherapy in adherence to guidelines that were in place. That was the nature of our questions.

M^{me} France Gélinas: That's good.

Deputy, again, please: Knowing the little bit that we know now, is the ministry, in its role of oversight of the health care system—are you interested in finding out if there are other such corporations providing services to our health care system, and are steps being taken to identify them?

Mr. Saäd Rafi: As I mentioned, in the working group, the hospitals affected are part of that group, but so is the Ontario Hospital Association. We have been talking with them at some length, but priority one was the patients. The next priority moved to, "Okay, so what do we know? What are we able to gather? Who has regulatory authority?" Now we're looking at how to deal with that regulatory authority and where the gaps exist. Then, yes, I think we have to turn our minds to the types of things that you're asking, but that is on our list of things. Of those 77 hospitals that provide cancer treatment—and I think that was the nature of that question earlier from Mr. Yurek—how are they procuring various drugs? Are third parties used in this regard? And then what are the quality assurance aspects? How do you receive the product? Do you receive it already combined but in a—I'm conscious of the experts in the room—sort of a bulk stock that you then break down to individual various doses to the nature of the patient? If you do that, do you do that in your hospital, and what are the quality assurance steps that you undertake? What are the mathematical applications you apply to that bulk stock? Do you get the vial instead of the product, and who do you get that from—through an outsourcer or direct from the supplier? And that's part of Dr. Thiessen's work as well.

The Chair (Mr. Ernie Hardeman): Two minutes left.

M^{me} France Gélinas: Okay, two minutes left. I'll use them wisely.

We all know that more and more hospitals are outsourcing more and more services, not only in drugs but in rehab, in patient transfer, in lots of services that used to be done and provided—services and programs that used to be within the hospital confines under their accreditation etc. are now being contracted out. I see the responsibility for the ministry to make sure that those programs and services are contracted out with accountability. Who within your ministry follows that? As more and more hospitals contract out more and more services and programs, who makes sure that those contracted-out programs and services have oversight, have accountability?

Mr. Saäd Rafi: Well, the hospitals themselves—that's a very broad question, and I don't want to short-change your answer.

M^{me} France Gélinas: I realize. Use your 45 seconds wisely.

Mr. Saäd Rafi: Well, I'm sure I'll be back, so I can embellish further.

Look, there's a legislative structure; they have their own corporate responsibilities; they have officers of their organizations; they have legislative accountability; they have procurement rules to follow. There are 154 organizations, \$17 billion.

I don't know that all the examples you used, either, were provided by hospitals in the past. Patient transfer was an ambulance-based service. Non-emergent transfer has been done for many, many years. I want to be careful that we're not indicting the hospital sector, writ large for this unfortunate and terrible circumstance, on many other things.

M^{me} France Gélinas: I have no intention of doing that.

Mr. Saäd Rafi: We do monitor the hospital activities. They have quality improvement plans. They report publicly. We have relationships with the hospital sector through the Ontario Hospital Association, and they have a legislative framework.

M^{me} France Gélinas: I'm more interested that once the service is in the community, and it is out of the hospital's responsibility, does it fall under yours, given that you have oversight of the health care system?

Mr. Saäd Rafi: Sorry, it's not our sole responsibility. Hospitals have to take a great deal of responsibility for every activity that takes place in the hospital. The Public Hospitals Act, as well as several other pieces of legislation, oversee their responsibilities as well. The ministry can't be expected in this—in the hospital circumstance, for every patient interaction, they have legislative responsibilities for their patients.

The Chair (Mr. Ernie Hardeman): That very much takes up your time. Thank you very much.

The government side: Ms. Jaczek.

Ms. Helena Jaczek: I'd like to go back to the chronology, because I think, in this very unfortunate incident, what is really important and one of the aspects we want

to look at is the response time in which the ministry took the actions that they did.

Mr. Sherar, as I understood it, the first notification to the Ministry of Health and Long-Term Care was March 29, I believe; the Good Friday. Would that have been correct?

Mr. Michael Sherar: March 28.

Ms. Helena Jaczek: Actually, it's March 28.

Mr. Michael Sherar: Which was the Thursday, I think, just before Good Friday.

Ms. Helena Jaczek: Thursday. Deputy, to you, in terms of this of this notification: At what point—perhaps we should even ask you—were you personally notified of this situation?

Mr. Saād Rafi: Easter Monday.

Ms. Helena Jaczek: Easter Monday. If we could just follow a little bit of what would have occurred with that notification to the ministry. Cancer Care Ontario, obviously, was engaging in a certain process. Was there discussion regarding patient notification and so on?

Mr. Saād Rafi: I think it's important to point out that prior to the 27th, when Cancer Care Ontario was officially brought in by the hospitals, these two particular hospitals had started to communicate with each other. Lakeridge/Peterborough—Peterborough is within the Lakeridge family—where the particular pharmaceutical technician—I don't wish to shortchange the individual, but this very clever individual realized a particular problem because they had just made a recent move over to this supplier—through a supplier.

1710

This individual, as I understand it, noticed a difference in the weight of the product. Again, I'm out of my depth, but I understand saline has a different weight than the actual combining chemotherapy drug. He decided to check, contacted his superiors and they reached out to London. I'm not entirely sure why London; I think they knew that they had a supply relationship through Medbuy. Then the other people using that outsourcing company got together and over the next six calendar days, as Mr. Sherar has pointed out, they started to examine, amongst their patient records, who would have had these drugs, when they would have started these drugs and what the impacts were. That became a very complex and operationally intense exercise.

So then Cancer Care Ontario was involved. I had a particularly challenging weekend on a personal matter. I was informed on the Monday. We started working with Cancer Care Ontario in earnest, although we had heard about this on the 28th or the 29th, every day for the remainder of that week. They issued a notice, I believe, on the 2nd—

Mr. Michael Sherar: A press release.

Mr. Saād Rafi: A press release notice on the 2nd with the number of patients, the affected hospitals, and then—I can go on for the rest of that week into this week, if you wish.

Ms. Helena Jaczek: Through that period, then, you feel confident that every step was taken with as much

speed as possible in terms of looking at the patients first, and that the process was—from your position as deputy, that Cancer Care Ontario and those individual hospitals were taking their responsibilities very seriously and they were working as fast as they can? Is that fair to say?

Mr. Saād Rafi: It is, and I say that because, of course, I was not witnessing the actual procedures put in place, but I know the CEOs of these facilities and I have come to know the integrity of the VPs of Cancer Care Ontario; I've worked with Michael since he was instituted—actually, just prior to him being instituted as CEO. These are all very, I would say, high-integrity, high-sincerity individuals who put the care of the patients of their facilities first, just like every hospital in Ontario does. I think they acted as swiftly as they could and at varying paces—I think that's already been chronicled—based on the complexity of the patient cohort they had.

Ms. Helena Jaczek: Thank you. So now, the actions that the ministry has taken since then: the appointment of Dr. Jake Thiessen—he's the third party expert reviewer—then you have the working group as well. I'm just trying to understand how the working group relates to Dr. Thiessen.

Mr. Saād Rafi: I would think of the working group as a resource to the ministry and, predominantly, Dr. Thiessen, in that he has the ability to ask very pointed and deliberate questions, because they happen to coalesce every day virtually on a daily conference call. He is using that first line of inquiry to then go out and do his visits. He's starting, I believe, with hospital visits this week. Then he'll have some preliminary assessment. As he says, drugs are his life. He has over 40 years of pharmaceutical experience, so he understands both the hospital environment as well as the combining and manufacturing end of this supply chain.

They're there as a resource. They're also there as a resource to us as we were trying to discuss and explain the various regulatory approaches, so that we come to a common set of understanding and conclusions to hopefully prevent this from ever happening again.

Ms. Helena Jaczek: I think somebody else may have touched on it, but the independent review will be made public, I am assuming?

Mr. Saād Rafi: I don't see why it couldn't be.

Ms. Helena Jaczek: Okay. Mr. Moleschi, just again trying to understand the jurisdiction here in Ontario—which I understand is maybe different from others, and we'll get to that—did Marchese Hospital Solutions have a pharmacist on staff within that corporate entity?

Mr. Marshall Moleschi: We were going in to discover that. They did have a pharmacist who was working there. They weren't listed with us, but when we went in to discover, there was a pharmacist involved.

Ms. Helena Jaczek: But would that pharmacist be someone in good standing? Their licence and—

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: Yes.

Mr. Marshall Moleschi: And that's why we have someone to do the investigation with.

Ms. Helena Jaczek: Okay. So with that knowledge, you and Health Canada are collaborating on this investigation.

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: And because of the grey area, you've both decided—

Mr. Marshall Moleschi: We wanted to see what was there—

Ms. Helena Jaczek: You wanted to see—

Mr. Marshall Moleschi: —gather the information and use our processes to make sure that the public could be assured that the system is safe, and we would do what is needed to be able to improve it.

Ms. Helena Jaczek: Right. Now, you made a point in your presentation that this section 118 of the DPRA specifies that the college does not have jurisdiction over “drugs compounded, dispensed or supplied in and by a hospital.” You were in BC. Are there other jurisdictions that have that ability to go into a hospital?

Mr. Marshall Moleschi: Yes, they do. They would be able to look at the processes in a hospital. They would look at the policies and procedures, the methods they have for detecting any errors, their quality assurance programs, the types of hoods they were using for the type of activity they were doing, because there are different levels for the different types. Chemotherapy requires a little more extensive—quite a bit more extensive—process than sterile compounding. Sterile compounding has higher standards than general compounding.

Ms. Helena Jaczek: Let's put it this way: Would you be advocating to have that section changed so that the College of Pharmacists here in Ontario would have jurisdiction in hospitals?

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: So I guess my question now, back to the deputy, is: How can we be assured of the safety, the quality assurance of hospital pharmacy now?

Mr. Saäd Rafi: Well, I think that's some of the work that Dr. Thiessen is going to help us better understand: give us an informed and expert judgment on whether the QA, quality assurance, practices were being adhered to, I guess. I say “I guess” because I don't want to say something that limits his activities.

In addition to that, he will look at, I would imagine, the contractual relationships and whether—if a company says, “We fulfilled our contractual relationships,” was the contract robust enough for ensuring quality? Because not every hospital is receiving these combined drugs in the same way, I'm led to understand.

That's part of the path of discovery that we're on. I think, as the registrar has said, this may take a few months. We want to be thorough, but we don't want to be so slow as to continue to have patients unduly worried—so trying to find that right balance to make sure that the right changes are proposed, be they regulatory, be they directives, by they legislative.

I think the registrar has indicated his interest in one specific area of the existing legislation, the Drug and Pharmacies Regulation Act, but there may be other areas.

In addition to that, we are asking the federal government to determine what it can do and what it should be doing with respect to the aspects of the Food and Drugs Act, where it has jurisdiction over manufacturing and preparing, amongst other things.

Ms. Helena Jaczek: Thank you. Now, my colleague, Ms. Gélinas, made reference to the Health Canada document that details their oversight of drug compounding. May I ask, Chair, that we have that document tabled so we can all have an opportunity to review that?

The Chair (Mr. Ernie Hardeman): Yes.

Mr. Saäd Rafi: Sure.

Ms. Helena Jaczek: I guess, if I have some time left—

The Chair (Mr. Ernie Hardeman): Oh, yes. You have, yes.

Ms. Helena Jaczek: Oh, good.

Mr. Sherar, obviously you have very broad experience with Cancer Care Ontario and elsewhere. Can you talk a little bit about the potential risk to these individuals? Just try and give us a picture of how the products may have been used. I know we all—obviously, when we hear “cancer,” everybody is totally, understandably very concerned. Could you perhaps, in the discussions that Cancer Care Ontario has had with its clinicians and so on, give us a picture of what this actually means?

1720

Mr. Michael Sherar: Yes. You know, I really appreciate the concern of patients and their families. Of course, we want to provide accurate information, not unduly alarming patients but giving a balanced view of the picture. This is a particularly difficult issue to kind of make conclusive statements on.

As you'll appreciate, there's very little or very sparse literature or evidence around under-dosing, so actually quantifying in terms of all of the patients who have been affected in the province—the impact on their particular outcomes, or as a group—is very, very difficult to do. That's why, I think, our focus with the hospitals has been that the issues around the effect that individual patients might have are best discussed with their oncologist. I think the hospitals have done a very good job of making sure that patients have the ability to have those discussions and have those questions answered.

I think researchers and Cancer Care Ontario and others will, of course, learn everything we can from this incident, to understand what the outcome may have been for these patients, whether it has been affected. I don't know the extent of how much we'll know in the future with respect to the outcome on individual patients.

As you're aware, probably from the press, these drugs are used in a variety of ways, for a variety of different cancers, for a variety of different intents: from a curative intent, where it's used in addition to, for example, surgery, to prevention of recurrence, to palliative care for treatments of patients who have advanced disease. Even though there's obviously a significant number of patients that we're very concerned about, the ability to make conclusive statements about the impact on patients across

all of those different uses of the drugs, the different stages of disease, is really very difficult to make.

I completely understand the difficulty that oncologists and others have in trying to reassure patients of what the impact may be. That's why I think our focus with hospitals has been, as I say, to make sure that they have those individual conversations. They can understand the likelihood of impact in a much better way. Whether there might be any increased monitoring of those patients or changes to treatment is really best discussed at the individual level.

Ms. Helena Jaczek: When was this product from Marchese Hospital Solutions first used? Do you know how far back we're going?

Mr. Michael Sherar: Yes. I probably don't know the exact date, but it was approximately just over a year ago, in early 2012. I believe both Windsor and London, early in 2012, started using this product. Lakeridge were much later, in the last month or so, and that's why there's a much smaller number of patients. As Deputy Rafi has indicated, Peterborough had just switched over. They work very closely with Lakeridge in the delivery of their systemic treatment program—and only one patient there, of course, as they have just switched to this product.

Ms. Helena Jaczek: So during that year or so, there haven't been any unexpected clinical things? People obviously didn't know about the situation. But there was nothing that was brought to Cancer Care Ontario as about, "Somehow things are not working the way they should"? There was no apparent change in outcomes that

was alarming during that time? I'm thinking of things that might be a little more reassuring for people, if that's at all possible.

Mr. Michael Sherar: No, we didn't receive any indication from hospitals prior to March 27 that there was an issue. No.

Ms. Helena Jaczek: Thank you. I'm not sure if my colleagues have any other questions. Otherwise, I think we're good. Thank you.

The Chair (Mr. Ernie Hardeman): I was going to say: You just can't sell that last two minutes, can you?

Well, thank you very much. That does conclude the time for today. As we said, we hope that you will be available again if the committee decides they need more information. Ms. Brown, I'm sure that they saved all the questions for you for next time.

Thank you again very much for being here today and enlightening us somewhat on the scope of the challenge that we're facing over the next number of weeks or months to come to some kind of recommendation as to how we can all make sure that this never happens again. Thank you very much for being here.

As for the committee, I just want to remind the committee that we need the names of the delegates that we wish to be asked to report by Thursday—the names that you wish to interview in future meetings.

With that, we're concluded until Monday at 2, same time, same place, to repeat today's events. The meeting stands adjourned.

The committee adjourned at 1726.

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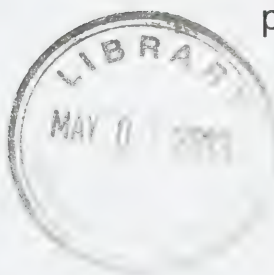
Lundi 22 avril 2013

Standing Committee on Social Policy

Oversight of pharmaceutical
companies

Comité permanent de la politique sociale

La surveillance, le contrôle et la
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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 22 April 2013

Lundi 22 avril 2013

*The committee met at 1401 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIESWINDSOR REGIONAL
HOSPITAL/HÔTEL-DIEU GRACE
HOSPITAL

The Chair (Mr. Ernie Hardeman): We'll call the Standing Committee on Social Policy to order. We are meeting this afternoon to hear depositions on a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

Our first deposition this afternoon is from the Windsor Regional Hospital/Hôtel-Dieu Grace Hospital. Each one can introduce yourself as you speak. We hope you do that. Introduce everyone, and everybody gets a turn to speak. That way, Hansard will have everybody's name—not only that, but they'll have it properly in the record rather than depending on my pronunciation.

With that, we also ask you all to go through the swearing of the oath, so I'll turn it over to the Clerk to do that.

The Clerk of the Committee (Mr. William Short): All right. I'll just go right to left. Dr. Ing?

Dr. Gary Ing: Yes.

The Clerk of the Committee (Mr. William Short): Do you have the Bible in front of you, or did you want to do the affirmation?

Dr. Gary Ing: I'll do the affirmation.

The Clerk of the Committee (Mr. William Short): Okay, so you can just raise your right hand, please. Dr. Ing, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Dr. Gary Ing: Yes, I do.

The Clerk of the Committee (Mr. William Short): Thank you. Mr. Schneider?

Dr. Kenneth Schneider: Dr. Schneider.

The Clerk of the Committee (Mr. William Short): Right; yes. Did you want to swear the oath or be affirmed?

Dr. Kenneth Schneider: Be affirmed.

The Clerk of the Committee (Mr. William Short): Can you just raise your right hand, please? Dr. Schneider, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present

inquiry shall be the truth, the whole truth and nothing but the truth?

Dr. Kenneth Schneider: Yes, I do.

The Clerk of the Committee (Mr. William Short): Thank you. Christine Donaldson: Did you want to swear the oath or be affirmed?

Ms. Christine Donaldson: I'll swear the oath.

The Clerk of the Committee (Mr. William Short): Okay. You have the Bible? Thank you. Ms. Donaldson, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Christine Donaldson: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Mr.—can you pronounce the last name?

Mr. David Musyj: MOO-shay.

The Clerk of the Committee (Mr. William Short): Do you want to do the oath as well? That's fine?

Mr. David Musyj: Sure. Yes, please; thank you.

The Clerk of the Committee (Mr. William Short): Okay. Mr. Musyj, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. David Musyj: Yes.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you all for that. At this point, we will advise you that you will have 20 minutes to make your presentation. Then we will turn it over to questions from the committee. This time, the questions will start with the third party. So—

Interjection.

The Chair (Mr. Ernie Hardeman): No, I think they had it first last time. My memory—you know, they don't come any better than that. But that's not the hearing; it's not about my memory.

With that, we'll turn it over to the panel.

Mr. David Musyj: Thank you, Mr. Chair. I'm going to start.

Thank you, committee members. My name is David Musyj. I'm president and CEO of Windsor Regional Hospital. I'm proud to say that I work with the most caring and compassionate team members at Windsor Regional Hospital. Today with me are three members of that team. Starting from my left is Ms. Christine Donald-

son, who's our regional director of pharmacy. Next, to her left, is Dr. Ken Schneider, our chief of oncology. Furthest from me is Dr. Gary Ing, our chief of staff.

Why are we here today? It's to provide answers to this committee, and also for us to get answers on how this possible medical error could have happen, to learn from it and to ensure it never happens again. We are all here to help get answers for the 290 patients and families that we harmed. Our patients who provide their trust in us and the system we work in deserve nothing less. It is their system. We all get paid by them, every single one of us in the room. We report to them.

There is a concept at Windsor Regional Hospital we hold near and dear to our hearts in everyday care. It is called "just culture." You might ask, what is just culture? Implementation of a just culture provides the cultivation of mutual trust whereby individuals are encouraged for executing safe acts or for submitting necessary information regarding safety. Organizations seeking to establish or maintain a just culture must realize that weaknesses need to be exposed and examined if systems are to be effective in enhancing safety. Just culture is also developing a preoccupation with failure or, in other words, becoming an expert at looking for trouble and doing something about it. Effective organizations treat all failures or near misses as windows on the health of the system and never stop fixing them.

What just culture is not: It is not blame and shame, so please, as you proceed down the road you are taking, do not blame and shame. Otherwise, if you do, look in the mirror first. We all wear this one. The only ones that do not are our bosses: the patients and families who we harmed and those we care for on a daily basis.

With respect to our approach to responding to this sentinel event, the three individuals who are here with me today formed a part of our response team that addressed this issue under the terms of our hospital's "Management of a Sentinel Event" policy.

I now will hand the podium over to Christine, Ken and Gary to introduce themselves in more detail.

Ms. Christine Donaldson: I am Christine Donaldson and I am the regional director of pharmacy services for Windsor Regional Hospital and Hôtel-Dieu Grace Hospital. I am a registered pharmacist in Ontario and have practiced for most of my career in hospital, the past 15 years in the Windsor community. I also hold a master's degree in education and was on faculty just up the street here at the University of Toronto, and remain an adjunct professor at Wayne State University over in Detroit, Michigan.

I became director of pharmacy at Hôtel-Dieu Grace first, in 2001, and then became a regional director of both Windsor hospitals in 2005. My key responsibilities are to advance pharmacy clinical programs, to lead safe medication practice and to insure a coordinated distribution system for all medications.

One of my current professional roles includes serving as a council member of the Ontario College of Pharmacists. The Ontario College of Pharmacists regulates phar-

macy to ensure that the public receives quality services and care. OCP council is comprised of 15 pharmacists, two of whom must represent hospital pharmacists, elected from the electoral districts of the province; two pharmacy technicians; between nine and 16 public members appointed by the Lieutenant Governor in Council; and two of the deans of the faculty of pharmacy.

Since November 2005, I also represent both Windsor hospitals as a voting member on the Medbuy pharmacy committee, which is part of the structure of this group purchasing organization. This role includes giving professional input to Medbuy's strategic team with respect to their contracting decisions and the request-for-proposal process.

I first became aware of this incident involving the chemotherapy drugs on the afternoon of March 27, after a pharmacy manager at London Health Sciences Centre called to alert us at approximately 4 p.m. All product within Windsor Regional Cancer Centre was immediately quarantined. After being notified, the fluid from one sample IV bag was extracted and it was verified that extra fluid was present in the bag beyond the labeled volume. With this result, I directed the pharmacy staff to begin preparing all cyclophosphamide doses in-house and patient-specific. This practice continues to today.

Immediately after London Health Sciences Centre staff notified us of the issue, we were contacted by Marchese staff doing the same.

In accordance with our internal policies and procedures, I notified the relevant vice-presidents and president and CEO later that afternoon, and we started to immediately investigate the extent of this drug error with respect to our patients.

On March 28, we started to meet as a clinical team to discuss the information we had received up to that point, continued to receive and continue to determine as a result of our internal investigation. On Thursday, March 28, our sentinel event management policy was in full implementation, with our CEO taking responsibility for incident lead, and a detailed plan was put into place with respect to notification of patients and families. The goal was to start notifying patients on Monday, April 1.

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This plan included verifying the names, addresses and phone numbers of impacted patients; creating a letter to be delivered to all impacted patients within 24 hours; creating a call-in centre for patients and families to call in after receipt of the letter and a call-out centre for all patients and families to be personally called even though they received the letter; appointment schedules prepared for patients and families to meet with their individual oncologists over a week-to-10-day period; and scheduling of town halls for families and patients to attend in group sessions.

Over the Easter weekend, we validated our patient treatment list, prepared our patient letter, created the call-in centre to ensure appointments could be booked simultaneously and seamlessly, and trained staff who were

calling patients on the process and to expect a range of emotions and how to try to address them.

While all patients were being notified, I also participated in three patient-family forums that were held to share our knowledge of the chemotherapy incident and to provide our commitment to learn from this event and to prevent future errors from occurring.

I would like to express personally my deep regret for the significant anxiety that this incident has caused for our cancer patients and for patients overall. I pledge to help to enhance the hospital medication system to make it safer and stronger for all patients so this never happens again.

Dr. Gary Ing: Good afternoon, everybody. My name is Gary Ing. I've been a family physician for the last 35 years in Windsor; I have been the chief of staff at the Windsor Regional Hospital for the past 18. I have many responsibilities, one of which is to collaborate with representatives of other disciplines to create an environment that promotes commitment to continuous improvement of patient care.

The changes in our health care system during the past 10 to 15 years were dramatic and unpredictable. I am sure that, as members of this distinguished committee, you are all well aware of the many challenges and constraints facing us currently.

As Canadians, we all take pride in having one of the best health care systems in the world. When an incident like this occurs, we need to refocus and critique ourselves on our processes. We have to identify any existing gaps and correct them immediately.

On March 27, 2013, we were made aware of the situation with cyclophosphamide. Windsor Regional Hospital took immediate action, with the patients and families being our focus. The next day, as you have heard, Mr. Musyj implemented our sentinel event policy. A team was assembled to develop a plan to address this issue. Over the Easter weekend, our team came up with an action plan. The primary focus was to disclose this matter to our 290 patients and their families as quickly as possible. We also had strategies in place to meet with patients and families to discuss their concerns. Within a week, all patients and families were contacted.

Going through this process, it is quite obvious that everyone has been adversely affected emotionally: the patients, their families, and our hospital staff. It also made us realize that our health care system is vulnerable to deficiencies of this nature. No matter what challenges lie ahead, we have the responsibility to advocate for our patients' safety and well-being. We intend to learn as much as we can from the findings of this incident and apply strategies to mitigate any potential risk in our other programs. Our patients deserve the best, and Windsor Regional Hospital is fully committed to outstanding care. Ken?

Dr. Kenneth Schneider: Thanks, Gary. Good afternoon, everyone. I do thank you for this opportunity for us to share our insight into this recent event. My name is Ken Schneider. I'm chief of the department of oncology

at Windsor Regional Hospital and physician lead in radiation therapy for the Erie St. Clair Regional Cancer Program. I've served in the role as chief for 12 years now.

I was born and raised in Windsor, and I was fortunate enough to return to my home community to deliver care to residents of Windsor and surrounding areas.

Besides my administrative responsibilities, I practise in a spectrum of disease site disciplines within oncology, including breast cancer, lymphoma and a number of other sites over the past 21 years. That's getting more and more painful to say, thinking back over 21 years of practice, but with each passing moment, there's one thing that really kind of resounds, and that's that I do this for patient care. That's what keeps me practising medicine.

I wanted to be a physician since I was eight years old. I parted ways with my appendix at that age, but became the proud owner of some old, dusty medical books from my surgeon; that's another story for another day.

A fundamental principle firmly embedded within the Hippocratic oath is the concept of "Do no harm." When scenarios such as this recent event occur, our initial instinct, as physicians, no matter what the root cause, is to ensure that further harm to patients is minimized, be it physical or emotional. Full and immediate disclosure of accurate information, an overriding principle of our institution's culture as a whole, followed by the steps as outlined by my colleagues, allowed the necessary management of our patients affected by this error. In addition, when an error occurs, it is critical to understand how it came about in order to learn from that experience and ensure that steps are taken to mitigate any future potential errors.

We must strive to minimize errors in the care of patients because we are privileged to have studied and worked very hard for this unique opportunity to serve them. For this reason, they place their trust not only in us but in the system. The professionalism, dedication and expertise of our hospital pharmacy program and staff are second to none. The precision to which their work benefits our patients is a daily standard. They will use this experience to gain even greater insight into the checks and balances to ensure patient safety.

As physicians, we respect that medicine is a complex blend of art and science, and of clinical judgment and evidence-based practice. The art component of medicine is the ability to use science with the evidence base that supports it while respecting the many unknowns that remain when studying the human condition and, hopefully, thus providing best care. This recent event requires us, as physicians, to counsel and guide our patients with our knowledge to the best of our abilities.

There's no data that allows us to confidently isolate this single factor of a variable dose reduction as to any deleterious effect it may have on our patient's outcome. However, based on (1) the many variables that remain unknown in cancer biology and therapeutics, and (2) the fact that a specific dose of a chemotherapy drug is prescribed based on clinical studies of that specific dose,

but not because one dose is the absolute required or only dose that will be effective, would indicate that the probability of a poorer outcome is very small. However, an absolute reassurance to our patients would be impossible, and we must acknowledge this. In addition, the emotional aspect of living with a potential risk of cancer progression or recurrence, no matter what the underlying reason, cannot be underestimated.

Ultimately, our role to these patients is to place this error into proper clinical perspective, respecting their concerns but encouraging them that, as physicians and as a respected health care institution, we will continue to advocate for best care always.

The Chair (Mr. Ernie Hardeman): Thank you all very much for your presentation. With that, we will start with the questioning and Ms. Gélinas.

M^{me} France Gélinas: Thank you so much. My first series of questions—first of all, thank you all for coming. I can guarantee you that we share the same goal that you do. I don't want harm to happen to anybody who has already had a tough time.

I realize that sometimes just talking about it, for some people it helps, for other people it brings more hardship, and I would say I'm sorry about this. The aim is not to harm them again. It's really for us to do the same thing you did, Mr. Musyj. You said in your opening statement that you want to learn so that it doesn't happen again. I want to assure you that this is what we're trying to do.

My first comment is to you, Ms. Donaldson. I was impressed by your resumé. You seem to be very active in the field. On your college also, I know that this is voluntary work that eats up a lot of a person's time. I take it that you know full well what the college does, that the college has oversight of their members, of pharmacies, etc. Did you know that this branch of Marchese was not regulated?

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Ms. Christine Donaldson: Yes, thank you. First off, I would like to echo as well the mandate of the Ontario College of Pharmacists, which is really one of public protection. All of the activities under the Ontario College of Pharmacists are to do that, to ensure the safety of the public members.

In the correspondence and the information we received through this process, there was some information shared with us regarding Marchese pharmacy that dealt with some issues around their accreditation status. We're still understanding that more fully, but it would be accurate to say that the information upon which we based some of our decisions was through the understanding of how they were regulated.

M^{me} France Gélinas: Just so that I'm clear, if we rewind to before March 27, before the first phone call and the series of events that is now well known to all, you had had a relationship with that supplier for how long?

Ms. Christine Donaldson: It was dating back to February 2012.

M^{me} France Gélinas: So for a full year you had had a relationship with them. I take it you've had relationships with other pharmacies and other members of the College of Pharmacists. Was there anything that would have led you to believe, from February 2012 and before March 27, that this grey area existed?

Ms. Christine Donaldson: At that time, we were under the impression that there had been some safeguards put in place. I think as the investigation unfolds, we'll continue to find out more about that, as far as what was the actual system process, or the system behind it, as far as regulation of compounding pharmacies. As you've seen in some of the dialogue between the regulatory bodies and our college, there was definitely some discussion, as we've said, before and after the event that has come to light.

M^{me} France Gélinas: So it's fair to say that when you entered into discussion with Marchese pharmacy, you basically went with good faith that the service they were going to provide to you was going to be provided by a body that had oversight?

Ms. Christine Donaldson: I think it's safe to say that, yes.

M^{me} France Gélinas: You took it for granted that the oversight was there because it's there everywhere else.

Ms. Christine Donaldson: Yes.

M^{me} France Gélinas: I won't put words in your mouth, but that's how you went.

If we look at prices—I don't know if you can tell me, but you're now doing the work in-house. If we compare this to the price of having it being done elsewhere, is it cheaper doing it the way you're doing it now, or was it cheaper when you had it done at Marchese?

Ms. Christine Donaldson: I think to answer that question I would just stress that the reason for us purchasing compounded medication in the first place was not based on price necessarily; it was actually around a safety risk that we had documented or had become aware of in terms of our own practice. It's the specifics of how this medication is actually prepared. It's very complex. As you know, in a chemotherapy preparation there's a series of very important steps that you need to take to ensure not only the safety of the product for patients, but as well for protecting the staff and the workers who handle the medication. In that case, really, cost didn't come into it as a factor. It was more safety and risk that had actually motivated us to choose this product from Marchese or another outside buyer.

M^{me} France Gélinas: Okay. Was there a series of events that led you to the point where you thought, on a risk-benefit analysis, the risk of doing it in-house—was there an escalation of risk? Because you have been providing chemotherapy treatment for a long time in Windsor.

Ms. Christine Donaldson: Yes, and again, we do provide the majority of our medication, chemotherapy medication included—it is prepared in-house. So this is one of only three items that we were actually having supplied to us by Marchese. Previous to that, we had been

using another supplier of this cyclophosphamide chemotherapy product. So there wasn't necessarily a series of steps or an escalation of steps, as you suggested. It was really part of our internal quality management system, I suppose, where it was addressed. Staff brought it forward; we made the decision to use an alternate product. And again, that is best-practice driven. Again, there are a number of standards that would support that type of procurement.

M^{me} France Gélinas: Are you comfortable now with having it done in-house? The risk of compounding those drugs has not changed significantly. There hasn't been any scientific breakthrough to make them safer to handle. Are you comfortable having them mixed in-house now?

Ms. Christine Donaldson: Just to reiterate, the majority of our chemotherapies are prepared in-house by our own staff, so this was just really one item that we weren't preparing, per se, in our own facility. It had just been added to our current structure. Our staff are already well trained, well versed, in preparing chemotherapy, and we have our own internal quality checks that, as you can imagine, continue to be our practice. Again, we'll be self-evaluating that practice as a result of this incident.

M^{me} France Gélinas: I'm trying to get a picture in my mind. You had identified some safety concerns—enough to decide to look at outside procurement. When this happened, you brought it in-house and everybody was comfortable with it? What's the difference between then and now?

Ms. Christine Donaldson: We need to be more clear regarding the specific chemotherapy preparation. It is actually procured as a vial of powder. Added volume has to be added to it by our staff. It then is a little bit more difficult to dissolve. It becomes a solution, and then it gets injected into the final IV solution. So it's really those stages and those steps that were adding a little bit of the complexity of the time, and that had led us to procure this other pre-mixed product.

M^{me} France Gélinas: Go ahead.

Mr. David Musy: Just to help out, the decision, as a result of this event, was to start making the particular product in-house. That decision will continue to be re-evaluated on an ongoing basis. I've discussed this with Christine, with other members of the hospital team: "As a result of this, how do we move forward?" It was with those discussions that we said, "For now, we're going to prepare it in-house and put the various safety mechanisms in place." As a result of all of these issues that are now coming to the surface, the decision of using another outsourced company to do this is not the decision we're making right now until it is settled about what is going on with respect to the accreditation, non-accreditation and oversight of these particular companies.

It's almost a day-to-day decision in the sense of a discussion with respect to, "Are we comfortable?" We made a decision in the first place to go outside, as you point out. As a result of this incident, we're now doing it inside. What has changed? Do we still have a concern? Through discussions with Christine and the team, no,

they are comfortable now with respect to this—far more comfortable than going immediately to another outside agency to do this—and have put into place the necessary safety restrictions for the benefit of the staff and, of course, our patients in preparing this drug on a per-patient basis internally. We've been doing that ever since March 27 and will continue to do that until there is some clarity with respect to the landscape that is going on, and some very clear focus with respect to the industry and oversight.

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M^{me} France Gélinas: Okay. Ms. Donaldson, you mentioned that before you dealt with Marchese, you also dealt with an outside procurement. Who was it?

Ms. Christine Donaldson: At this point, we had partnered, through a previous contract, with another CIVA—central intravenous admixture, sorry; I'm using an acronym here—service provided by Baxter Corp.

M^{me} France Gélinas: By Baxter? Okay. And how long had you had this procurement with Baxter?

Ms. Christine Donaldson: The cyclophosphamide product: It had been since July 2011.

M^{me} France Gélinas: Okay. And what made you change from Baxter to Marchese?

Ms. Christine Donaldson: There was a contracting decision—an award through our Medbuy organization that had prompted the change.

M^{me} France Gélinas: So Medbuy went for an RFP? Okay. And I take it that Marchese was the happy winner—

Ms. Christine Donaldson: That's right.

M^{me} France Gélinas: —of this procurement. Okay.

I'd like to come back a little bit. In your answer, you make it clear that you want to make sure that there will be accountability. You're willing to take the risk of mixing those drugs in-house and will make future decisions once the accountability issue is settled. Had it ever occurred to you that the accountability could rest anywhere but with the Ministry of Health? Did you ever think that it was your responsibility to do that oversight, that it was a hospital responsibility to check on oversight?

Ms. Christine Donaldson: I'd defer that to David to answer.

M^{me} France Gélinas: You get the tough questions.

Mr. David Musy: Sure. With respect to that answer, it could possibly be. We're part of the problem here. As I stated in my opening statement, now is not the time to point fingers; it's the time to learn about how this happened. So we're participating in a review that's being conducted by Dr. Thiessen, and we look forward to his comments. We met with him last week as a team, and we look forward to hearing from him with respect to what he finds.

Where does the responsibility lie? What changes can we make as a hospital and as hospitals, because it's a system issue, that could avoid this happening in the future with respect to this drug—or any other drug, for that matter? At the end of the day—I can tell you, when

we met in our town halls with the patients and families—yes, when we got the IV bags, could we have weighed them? Sure. Could we have pulled every 10th or 20th bag, extracted saline out of it and measured every bag ourselves? Sure. We talked about that openly with our patients and families.

Is that reasonable? This is one of, to my understanding, some 2,000 different types of drugs that we dispense out of the hospital on a daily basis. Is that reasonable? Should the oversight happen at the source? Should it happen at the hospital? Should it happen at both places? That's what we need to learn. Those are the answers we need to get. Those are the reflections we've had internally. Now we need to have them as a system and, as a part of this review, learn from it, and figure it out so that this never happens again to this particular drug—or any other drug, for that matter.

M^{me} France Gélinas: You've mentioned that you've already started to meet with Dr. Thiessen, who will be doing the review. Who will be invited to talk to him, or who will he talk to at your hospital?

Mr. David Musyj: He talked to our whole incident team. He was given wide-open access to talk to anybody whom he wished to talk to at the hospital. He met with a broad selection of individuals; all of us here at the table he met with, and our full sentinel event team, which contains nurses. Then he went to the actual area in which the drug was brought into the hospital, and also dispensed to patients and provided to patients. He was able to talk to anybody and everybody he wanted to, and he's more than welcome to return if he needs to have follow-up.

M^{me} France Gélinas: If he reaches out, you make them available. Is it true in reverse? As in, if somebody from your hospital wanted to talk to him, how would that go?

Mr. David Musyj: They can contact him directly if they wish to, but they have a opportunity to do so. At any point, if anyone wants to talk about this to anybody, I would ask them to reach out to him. There is no restrictions on his availability to talk to anybody or hear from anybody.

M^{me} France Gélinas: Would you say that the same thing applies to this committee, if we wanted to talk to some of your staff?

Mr. David Musyj: Yes. I wouldn't want you to be calling them in the sense of—but if they want to talk to you, if you call them directly and they wish to talk to you, more than welcome. As long as there is no breach of patient confidentiality, I have no issue with respect to that. So if you want to talk to people—I'm not going to give you their home phone numbers. You can have mine if you want.

M^{me} France Gélinas: No.

Mr. David Musyj: Yes, more than welcome. Anyone is welcome to discuss this issue with the staff. What we tried to do, though, for our staff—because our staff will be asked by patients and families about this particular issue—we've said to staff, "Please direct them to this phone number." We had a call-in number for patients and

families to call in. So we make sure we are talking to the patients' families, in the sense of giving them the information.

The last thing—and I use this as an example—is for a patient or a family to see me out in the community, ask me a question and assume the answer I'm giving them with respect to this event resolves it for them. We wanted to make sure, "No, you need to talk to this call-in centre, because the person you need to talk to to get your answers is your oncologist," be it a patient or a family member. "That's who you need to talk to, not David Musyj, president and CEO. I can provide you as many answers as I can, but you really need, on an individual basis"—so that's where we try to direct everybody. Successfully, we've been able to do that. A patient or a family member who wants to talk to their oncologist about this has had the opportunity to do so.

The Chair (Mr. Ernie Hardeman): You have two minutes.

M^{me} France Gélinas: I'm going to keep my two minutes.

The Chair (Mr. Ernie Hardeman): Okay.

Ms. Jaczek.

Ms. Helena Jaczek: First of all, I'd like to echo some of the comments made by my colleague Ms. Gélinas in terms of what we're trying to achieve here, which is clearly to learn from this experience, and, from the government's perspective, are some of the measures that we've put in place since we heard about this particular incident appropriate?

Just to start off, as a physician, I feel very much, as the physicians in the room, and I believe all of us, that this is something that from the patient perspective is clearly a scary situation. Dr. Schneider, you made the comment that even though the probability of poorer outcome is very small, absolute reassurance to our patients would be impossible, and we must acknowledge this. The whole emotional context here is very important, so I was very pleased to hear about the town hall that you held there to talk to patients and families.

From a clinical perspective, and perhaps to Dr. Schneider: Over the last year, since this product was in use, had you noticed any changes in terms of predictable patterns of cancer progression or regression? Was there anything unusual that you had been following?

Dr. Kenneth Schneider: That's a good question. In terms of the population that's treated with this particular drug, the two main populations are breast cancer in the adjuvant setting where cancer has been removed; cyclophosphamide is one of a combination of drugs given to minimize the risk of recurrence. The other proportion of patients is non-Hodgkin's lymphomas, where you're giving the drug for a measurable disease that's still present. In neither of those groups was there anything from my physician group that they indicated after hearing of this, "Gee, that's interesting. I could relate that to a difference in clinical outcome." There's nothing that would substantiate that, and it's likely because, in the breast population, there's no disease to measure. It's

given on a preventive basis. There were no uncommon, unusual increased relapses within that period of time. In the lymphoma population, it's one of a combination of effective drugs where the response rates are actually very good. Nothing really fell out in terms of identifying a clinical change.

Mr. David Musyj: Just to follow up, because I think it's timely: one of the things we learned from the town hall that came up—because what's amazing is, patients and families, as you know, stricken by cancer, as everyone knows, have insight that, to this day, I marvel at. To a person, in each of the independent town halls, they were very similar, and one of the issues they brought up: "Could we be used as a test group moving forward? Could we talk and have the approximately 1,200 individuals be monitored to determine if there is any measurable outcome?" That was one thing that came up, and I think there's actually work under way outside of this to have a review. Because unfortunately, from the literature—and correct me if I'm wrong Dr. Ing or Dr. Schneider—there is very little literature out there about the impact, negatively, as a result of underdosing at this level. So your point's well taken.

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Ms. Helena Jaczek: Thank you, that's very helpful.

Now to Ms. Donaldson: Just so I fully understand, since February 2012, Marchese Solutions delivered to the hospital IV bags with what was assumed to be the appropriate dose. We've heard that there was something like a 20% reduction in the dosage, so that the dilution had, obviously, been increased. This isn't to point fingers. I'm sort of surprised that a 20% increase in saline wouldn't have been fairly noticeable. Can you just lead me through that?

Ms. Christine Donaldson: Absolutely. It's a good question. Again, we did a bit of a show and tell with our patient family forums and brought them an example IV bag just to explain the process, because it's a well-known industry standard; I'll call it that. A pre-filled IV solution bag would have more than the stated volume. So in other words, we're talking about an IV solution bag that had 250 millilitres from the manufacturer. In this case, it was Hospira. That was the known overfill. So the known stated volume was 250 millilitres; however, it's a known industry standard that there's 20 to 30 millilitres higher than the 250 in each bag. If you actually hold them up side by side—it depends on how much air is within the IV bag, it depends how it's been manipulated, it depends how long it's been out of the overwrap packaging—the real difference, even to the naked eye, would be highly difficult to distinguish. I think that's an important point to bring out. It's a clear-colour solution. The staff handling or looking at the drug—or the labeled amount that was there—it would be very difficult for them to distinguish that 20% difference.

Ms. Helena Jaczek: Thank you. Then nothing was done within the hospital to further dilute—you didn't touch it; it was literally, "This is the IV bag. This is what got hung."

Ms. Christine Donaldson: Right. I'll just explain that a little bit further. The oncologist would actually prescribe a dose, to the milligram, because it's important in cancer chemotherapy that it's very much determined by the patient's weight and other status. The dose would be drawn up, the number of millilitres that would result from that dose from the bag of saline solution with the chemotherapy in it, and then that amount, that specific volume for the patient, was then injected into a small mini-bag that was then delivered to the patient. There was no further dilution; however, it was actually injected into the mini-bag and then the entire amount of that second mini-bag was actually administered to that specific patient, as per their oncologist's order.

Ms. Helena Jaczek: Okay, thank you.

Now I understand that the actions that you took—we had them detailed to us by Michael Sherar last week. Windsor was—I was impressed by a rapid response in terms of the actions that you took. Can you talk to us a little bit about your communication with the Ministry of Health and Long-Term Care? When did that occur and how has that conversation continued?

Mr. David Musyj: I can speak to that. Back when we found out about this as an organization—late Wednesday, later in the afternoon, into the Thursday—I recall specifically, as part of our policy, reaching out to the Erie St. Clair LHIN and informing them of this particular incident. You have to remember that at that moment, late Wednesday into Thursday, it was trying to pull this information together with respect of what actually occurred, how many patients did it possibly impact. So it was a lot of information gathering, trying to get as much information as possible. So notifying the Erie St. Clair LHIN and ensuring that, either through CCO—Cancer Care Ontario—or through our Erie St. Clair LHIN, the Ministry of Health became aware of it immediately over the Easter weekend as well, or at least that, "There is an issue; we're investigating it and trying to get as much information as possible." That would have happened, at least from our point of view—I know that some other hospitals were aware of this issue in advance of us, so we were, from my information, last to know about this particular issue until London Health Sciences Centre called us at approximately 4 p.m. on the Wednesday. Does that answer your question?

Ms. Helena Jaczek: Yes. Since then, what sort of communication have you had with the ministry or the LHIN or Dr. Thiessen or the working group or—

Mr. David Musyj: Ongoing and non-stop. With respect to our internal sentinel event management team, we started meeting that Thursday, and we met every day officially, had minutes of those meetings, and had discussions with respect to exactly what needed to be done in order to focus on the patients and the families and get notification as accurately and as timely as possible in as sensitive a manner as possible. In addition, ongoing communication: keeping the Erie St. Clair LHIN up to date as well as the Ministry of Health. As president and CEO, I'm on a working committee that has a phone call

daily with the Ministry of Health and the other hospitals involved regarding this particular issue and talking about broader system issues and moving forward. For instance, with the draft regulation, being notified that it's coming out, with the attestation document, and trying to move forward. It has been non-stop communication with the Ministry of Health and the Erie St. Clair LHIN.

Ms. Helena Jaczek: Since you've touched on the draft regulation, could you perhaps describe this for the committee and tell us what kind of impact it's going to have on patient safety?

Mr. David Musy: Sure. We just got the draft regulation late Friday, and there is a 15-day period to get feedback. Christine has been asked to provide us some feedback. We'll be doing that and we'll be reaching out to the other hospitals and system players involved to find out what impact—because the last thing we want to do, of course, is to create a bigger problem trying to solve another problem. I appreciate the fact that there is this 15-day period for hospitals and other health care providers to provide comment; that there wasn't some unilateral implementation of a regulation that could create a bigger problem than the one we're trying to solve. That's what we're working through right now. But I can tell you, as a hospital system, in addition to this, our focus from day one, since March 27, has been focused on the patients and the families and our own staff in addressing this issue. We haven't, since Friday, had a considerable amount of time to look at the regulation and examine the impact of it.

Ms. Helena Jaczek: Ms. Donaldson, could you describe what's in the regulation?

Ms. Christine Donaldson: Sure. From my review, it does state that there would be some, I'll call them provisions, that would be more fully detailed as to how hospital pharmacies could procure medication, specifically IV-compounded medication, outside of its own facility. It does just basically lay out the provisions that would be necessary before that sort of arrangement could—

Ms. Helena Jaczek: With some sort of oversight of these facilities?

Ms. Christine Donaldson: Right. In different details, it does describe that there would need to be some sort of regulation or an accreditation status or some other type of, as you said, oversight to the supply chain.

Ms. Helena Jaczek: Could you please describe to us your ongoing quality assurance program with respect to pharmacy within-hospital?

Ms. Christine Donaldson: Thank you, and it was something I did want to note for this committee. Again, I'm very proud to be a member of the Windsor Regional Hospital staff. We have had a very strong quality-management system in place for a number of years. Many quality indicators are continuously monitored, and data is collected and action plans result. Specifically, medication incidents have been one of the top quality indicators for our entire institution. Again, this is public on our website. I encourage you to take a look at some of the success.

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As we outlined in our original statements, it's an on-going, constant challenge to learn from the system and basically challenge each other on where the gaps are in the system. That way, we can continuously improve. For example, I am a co-lead of a working group. We meet weekly. We review all the med incidents that happen, or near-misses, which again is an opportunity to learn from a potential error before it actually reaches the patient, and we have discussions around what we could do to make the system stronger, including adding extra safeguards—extra safety measures and steps—within our own facility. That has been a long-standing practice.

Obviously, with this situation, we'll be continuing to do our own internal investigation into additional practices that we can put into place to ensure that we are, again, following those quality measures, including double-checks—you talked earlier about weighing the IV bags—anything that we can do to, again, ensure that the quality of our own product is of the best standards.

Ms. Helena Jaczek: Currently, when you talk about incidents, is this where perhaps the pharmacy sends a particular medication to a patient and the individual administering that substance or product notices that there is something that doesn't jibe?

Ms. Christine Donaldson: That's correct. It could be self-disclosing. Again, we have a very strong framework at our hospital, so we encourage reporting of incidents so we can learn from the system. It may be as simple as omitting a dose due to another patient care issue: A dose of another medication is omitted or given late. Again, we would encourage the nurse to submit that incident, put any of the reasons or the root causes behind why they believe that incident occurred, and then we start to discuss what we can do to strengthen the system around that individual nurse's practice or the pharmacy's practice.

As you said, it's very much a multi-disciplinary team approach. Again, as this incident shows, you're constantly challenging yourself to look for those gaps, because often you don't know they're there until you continuously look for them.

Ms. Helena Jaczek: And who do you report these incidents to?

Ms. Christine Donaldson: We have a vice-president who is also an active member of that team, and then all the quality indicators and action plans trickle up to our quality improvement plan for the entire hospital. So again, that's very much the flow of how that information goes forward.

Ms. Helena Jaczek: This is the quality-improvement plan pursuant to the performance agreement that you have with the ministry?

Mr. David Musy: Yes. These medication errors are publicized hospital-wide. All front-line staff, our board quality committee—as Christine identified, our medication incidents are notified to the whole community on our website. But yes, it's tied back into the quality improvement plan pursuant to the Excellent Care for All Act. That's where the tie-in is.

Ms. Helena Jaczek: These do get reported to the LHIN and subsequently, presumably, to the ministry.

Mr. David Musyj: They are there for the world to see.

Ms. Helena Jaczek: Thank you. Now, Health Canada also has made some improvements, as we understand, mostly from the media, over the last few days. What are you aware of in terms of what Health Canada has done in relation to compounded drugs?

Ms. Christine Donaldson: At this point, we were asked to—I'll call it respond or indicate practices within our hospital sites that involve sterile IV compounding, including whether or not we had the facilities—human resources, proper practices—to continue or bring those practices in-house, similar to what we have done as a result of this incident. I also know that each facility will be asked, as David outlined, to complete an attestation form that would indicate how those quality assurance practices are in place to, again, ensure protection of the public; that that is a little bit more transparent, I guess I'll call it, to the public eye. Again, we've been asked to summarize our practices, and that is within hospital sites as well.

Ms. Helena Jaczek: Thank you. How much time do I have left?

The Chair (Mr. Ernie Hardeman): Two minutes.

Ms. Helena Jaczek: I'll keep my two minutes, as well, for the second round. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. With that, we'll go to Mr. Yurek.

Mr. Jeff Yurek: Thanks, everyone, for coming out. A long drive from Windsor—or a train, I guess; whichever was quickest.

Just a few questions, and then Christine will cut in here. Can you give me your view of Medbuy—how it operates, what it entails and the partnerships involved in it?

Ms. Christine Donaldson: Sure. I can start off by explaining my understanding. Medbuy is a group purchasing organization which Windsor Regional Hospital joined in 2005. It does a number of procurement actions, but specifically in the pharmacy realm. There is the strategy around Medbuy's—every single hospital that becomes a member of Medbuy has a senior executive on their board, and essentially Medbuy exists because of the member hospitals that represent those sites.

As a pharmacist leader, I was asked to participate on the Medbuy pharmacy committee—that's exactly what the name is—and it's essentially an advisory group. We meet monthly by teleconference and also twice a year face-to-face to discuss current issues. Everyone remembers too well the back order situation last year with our Sandoz supply, and as a result of those sorts of challenges, the team got together and created a list of 30 critical medications that must be a part of our strategy in terms of perhaps allowing dual awards to be given out to pharmaceutical companies, to prevent that sort of back order situation or shortages in the future.

We tend to have a very professional or advisory capacity at that level, really guiding some of the practices

into the future for the pharmaceuticals that we would ask Medbuy to procure contracts for us.

Mr. Jeff Yurek: So at the end of the day, when you entered into an agreement with Baxter in 2011, and then Marchese, was that Medbuy or was it the hospital?

Ms. Christine Donaldson: Yes. There was a contract, as you said, in place and, again, part of the procurement guidelines is to—I kind of forget the name of it—issue a statement of single source?

Mr. David Musyj: Yes. Maybe I can help. What happened is that we, through Medbuy, had a contract, with all of the other hospitals, with Baxter. When that contract came up for renewal or expiry, from the information I have, there was notice that was posted. There was a thought, I guess, by Medbuy that Baxter was the only company that had the ability to continue the contract past the expiration, so they had to file a notice, which was publicly posted, wanting to sole-source, meaning wanting to continue with Baxter. The information I have is that Marchese at that point filed an objection to that sole-source. As a result, Medbuy had to go to the market at that time, went through a full procurement practice, and Marchese ended up being the successful proponent of the RFP.

Mr. Jeff Yurek: So Medbuy coordinates the procurement and the request-for-proposals?

Mr. David Musyj: They handle all of their procurement process. Now, as Christine outlined, she is one of the individuals in this particular contract that was involved in the procurement practice. Christine can talk about it; she can talk about how many people were on the procurement team. Everyone kind of has their own little slice of the RFP process that they evaluate and score, and then that goes back to Medbuy with respect to the eventual totalling and then seeing who was the successful proponent. If you want more detail, Christine can provide it.

Mr. Jeff Yurek: Yes, if you can just do an overview of what you actually looked at when, say, comparing Baxter to Marchese or to any other product or company.

Ms. Christine Donaldson: Sure. As David outlined, I can only tell you my slice, right?

Mr. Jeff Yurek: Yes.

Ms. Christine Donaldson: Certain components were shared with the entire group and then, as you said, there were a number of individual—I don't know the total number. I would say it was between eight and 10 pharmacy committee members—so, again, directors of pharmacy similar to myself for the Medbuy hospitals—that were given three or four elements of the criteria. We also helped to give the relative weighting of the criteria for the RFP, and I think that was an important step to involve the pharmacy committee members. As you can imagine, when you're being scrutinized for decisions—our committee has a very strong mission statement around quality over financial. If you look at the scoring criteria, "financial" is the smallest percentage overall, actually, in the weighting of the RFP. Other pharmaceutical criteria, business criteria and quality criteria were much more heavily weighted.

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I was essentially sent those three or four items off the RFP, asked to score them—there were actually three companies that came forward that met the initial cut-off for the RFP—and then we sent back our scoring to the Medbuy strategic team to then go ahead, collate, and continue to come up with the final award.

Mr. Jeff Yurek: Do you know if there was a pre-qualification for companies wanting to bid at Medbuy? Was there something set out in Medbuy that would pre-qualify them to allow them to go after contracts, which would check their references, check their ability to do the job, the previous history at performing that task?

Ms. Christine Donaldson: I believe that was part of the process. If you look at the RFP, those criteria had asked for some business criteria, producing any practice standards that they were meeting; those sorts of things. They were embedded almost in the—I don't know if I would call it pre-qualification, but I don't know if there were any more—for example, I know there were three bids that were assessed by our team, the pharmacy committee. I don't know if there were any more that were submitted and basically didn't meet the RFP language, but what was shared with us was that there were three successful companies interested in this business that had met the criteria, and we would continue to score them from that point on.

Mr. Jeff Yurek: But in that vetting process, though, the ability to see if Marchese was qualified or not—or oversight on this, OCP or Health Canada, if they were a compounder or a manufacturer. I know it's a really grey area out there, but—

Ms. Christine Donaldson: I know they were asked to submit, as part of the RFP, any standards, qualifications and certificates to show they were meeting any of the accepted practice standards. I believe that was embedded in the RFP process, but I wouldn't say it was, like I said, a pre-qualification.

Mr. Jeff Yurek: Thanks. Does the Ministry of Health deliver any guidelines to Medbuy or to the hospitals on procurement of medications? I wouldn't say equipment and such—that's a different category—but any guidelines for procurement standards that they should be achieving through the hospital's procurement of outsourcing?

Mr. David Musy: Overall, just with respect to the broader public sector guidelines and directives with respect to procurement, they are rather detailed, not so much through the Ministry of Health but through the Ministry of Finance. We have very detailed directives with respect to what to procure, at what level do you have to start the procurement process and the whole details, and that covers not only drugs; that covers equipment; that covers paper; that covers pencils; that covers everything we purchase at the hospital.

Mr. Jeff Yurek: But nothing from the Ministry of Health that's saying, "If you're going to outsource this medical product, it has to have a certain standard that would be equal to or better than what you could produce in-house" or anything like that?

Ms. Christine Donaldson: I would answer that question by referring back to our initial comments around quality and safety. There are a number of standards that are out there that—the College of Pharmacists puts out standards; the Institute for Safe Medication Practices puts out standards. I think that is constantly part of the evolution of safety and practice. That would help inform our decision-making. There are guidelines published as well through the Canadian Society of Hospital Pharmacists. We would also follow their best practices. So I think it comes from many arenas in terms of indicating or directing our practice toward the best possible standards. There isn't one overarching guideline.

Mr. Jeff Yurek: Just two quick questions: Do you outsource any other compounded medications?

Ms. Christine Donaldson: No.

Mr. Jeff Yurek: And how are the bags coming from Marchese labelled?

Ms. Christine Donaldson: Sure. We did provide, actually, an example in our patient-family forums to help explain what we had experienced.

The label itself does list four grams of cyclophosphamide in 200 millilitres. That's how it informed us of the final concentration or stated concentration.

Mr. Jeff Yurek: The concentration wasn't on the bag, though?

Ms. Christine Donaldson: No, the concentration was not specifically listed on the bag. However, the total drug quantity in milligrams or, in this case, grams, and the total number of millilitres was stated.

Mr. Jeff Yurek: Christine, thank you.

The Chair (Mr. Ernie Hardeman): Jane?

Mrs. Jane McKenna: Thank you very much. My question is actually to Christine. Marchese maintains that its drugs were not defective, suggesting the problem was how the drugs were administered at the hospital, not how they were prepared. How do you react to that?

Ms. Christine Donaldson: Again, our concern is for our patients. That is paramount. The word "defective," I guess, has many definitions. Do I believe that there were the stated milligrams, the right drug, in that product, in that package? I do. We haven't done a qualitative analysis ourselves. I believe that there was a product produced according to what they believed the final concentration should be for our facility. Unfortunately, I think there was not that oversight, as you said, as far as the product produced and what the intended use was for our patients. I think that's where I'm challenged in terms of clinical practice and intended use of cyclophosphamide for cancer patients.

Again, I sort of take issue with that word "defective." Do I think it was prepared with the proper steps and the proper quality practices? Likely it was, and I guess the investigation will continue to help us delve into those issues, and hopefully we await Dr. Thiessen's report to share the outcomes so that we can improve the process from this point on.

Mrs. Jane McKenna: Thank you. My next question is this: I understand and applaud your commitment to

quality improvement, but what quality assurance processes are now in place, now that these drugs are out-sourced?

Ms. Christine Donaldson: Thank you. Our current staff, again, are trained staff in product preparation, including for chemotherapy. In fact, all of our technicians are on the path to become regulated by the Ontario College of Pharmacists. The level of steps is probably between six to eight of product selection, a double-check to make sure that the right vial and the right IV bag are selected against a label that has already been reviewed by our pharmacist. Our pharmacist team actually produces—part of their internal quality checks is to double-check the prescription that is written by the oncologist; it's actually locked down. The label and the product cannot even be released until the pharmacist reviews it for accuracy and also for patient-specific lab results, etc.

At that point, then, as I said, one technician would procure the two items, the two products. A second technician would check that. Then the volumes would be withdrawn. Again, another set of eyes, another technician would be responsible for double-checking that process. Then it would be injected and it would be labeled appropriately, and then more checks. In almost every single one of those steps, staff have to initial and validate that they've taken those steps. Really, between the point when a physician actually writes a prescription to when it's actually handed over to the nurse to deliver, again, there's probably between eight to 10 safety checks that happen.

Mrs. Jane McKenna: Thank you very much. I just have one more question to Dr. Ing. Unpredictability makes any system vulnerable. I just wanted to know if you could elaborate on what you said in your opening remarks, that the last 10 to 15 years have been very dramatic and unpredictable.

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Dr. Gary Ing: My intent of that statement is this: We all know that we are under pressure in terms of the health care system, in terms of our resource allocation, demand by the population that we serve, and also the expectation that we have to provide the best care that we can in Ontario and also in Canada. So when you look at all these various factors, they are not necessarily on the same page. There are ups and downs and variability.

As a health care institution, we have to be responsible and we have to be creative and also make accommodations so that we can juggle the financial aspects, the demand, the quality of care, the efficiency. We've got to balance all those factors such that we can provide a service that we're supposed to to a community. That's why this is unpredictable, because this particular incident like this—how can we predict that to happen? A lot of things we carry out in practice. Standard practice is the way we practise, and the expectation is that when we receive a particular product or medication, we expect it to be the true, pure medication.

If I prescribe penicillin to my patients, when the pills come down from the pharmacy, we expect it to be

penicillin. Unless there's some other appearance of a drug or something that would tip you off, you wouldn't know that. Then what you do is, you trace back to the processing like this, to the company and so forth. There are many, many generic companies out there for penicillin, for one thing. That's why it's very difficult when you don't have the awareness, and I think this particular incident really heightened the awareness for us. As you look at the various steps in the system, there are a lot of partners involved and a lot of people have to play a part, including the hospital ourselves here.

We certainly take full responsibility in terms of what we do, but we are also learning now from the investigators, from your committee and various sources as to how we can prepare ourselves to mitigate the risks in the system and to improve this. Even though it is a very tragic event, so to speak, we need to make something positive out of this. I do believe that if everyone is willing, we can make this a more positive story down the road.

Mrs. Jane McKenna: Thank you.

The Chair (Mr. Ernie Hardeman): You have about two minutes left.

Mrs. Christine Elliott: All right. I'll try and make the most of it, then. I'd like to go back, if I could, to the original decision in 2011 to actually begin purchasing the prefilled solutions. I guess my question would be directed to Dr. Schneider and Ms. Donaldson. How did this decision come about? What precipitated it? Was there an incident or was this just something that came forward as best practices, and where did it come from? Was it physician-led, pharmacy-led, or how did it come about?

Ms. Christine Donaldson: It was pharmacy-led. As I tried to outline earlier, it was part of the practice—the safety. It came forward from staff, actually. Our own pharmacy staff came forward, in discussion with the current supplier, Baxter: Would this be an opportunity to have a compounded or a premixed solution as an opportunity to meet that quality practice? So it wasn't oncology-driven. There was no incident per se that prompted that. Again, it was more of a safety decision that had alerted us to the option.

Mrs. Christine Elliott: And what was the process for getting that approval? Was that discussed with the medical staff or was that just a decision that was made in pharmacy, and were medical staff aware of it?

Dr. Kenneth Schneider: As physicians, we're really the end-users. We're really not involved in the specifics of a process of how a particular drug is purchased, because of the fact that when you work in an environment where there's expertise at various levels and various programs, physicians don't weigh in on all those discussions.

Mrs. Christine Elliott: But this would have been a fairly significant change, would it not, and did it require any kind of approval in order to be able to proceed in this manner?

Ms. Christine Donaldson: I would just go back to indicate that the typical hospital practice for many years

has been—and again, this is not just within our site—to have compounded IV medications, whether it be antibiotics—and again, the list of products we're talking about here—cyclophosphamide was one of them, but there's an A-to-Z list of many items that are available in a premixed format. So again, that has been a relative norm—I guess I would call it a practice—to select some premixed products, again, with the rationale beyond actually getting the pure or the individual vials and compounding it in-house. That has been a long-standing practice.

Mrs. Christine Elliott: Thank you.

The Chair (Mr. Ernie Hardeman): Just a very quick comment: That concludes the time for the party, but—

Dr. Kenneth Schneider: Thanks very much.

The Chair (Mr. Ernie Hardeman): You wanted to make another comment?

Dr. Kenneth Schneider: I could maybe weigh in on where physicians do have a role, and that's more in the area of pharmacy and therapeutics, or MAC, where there's a therapeutic change in a dosing of a drug or there's a significant change in the indications for the use of a drug. That's where typically physicians would have input to make some decisions. That wasn't the case here.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time. Did you want your last two minutes, Ms. Gélinas?

M^{me} France Gélinas: Yes, please. I will be very brief. Either to Dr. Ing or Dr. Schneider, whoever wants to take the lead: I think, Dr. Schneider, you said it best. You work in an environment where there's expertise at many levels. Lots of what you rely on is made in the hospital, is an activity of the hospital, but lots of it is also for a partner in the community. I'm sure some of your patients go to labs in the community and have ultrasounds and X-rays and have all of this. But there is always that level of trust that when they go outside of your hospital walls, there is a level of oversight that is there so that the result you get back, whichever partner it comes from—the products that you get—was always—

Dr. Kenneth Schneider: You hope for it to be reliable.

M^{me} France Gélinas: Yes, you hope for it to be reliable. Has this shaken your confidence in other parts of the system, that if a pharmacy—what we thought was a pharmacy, with the oversight of the college and everything else—can make a mistake like this—does that make you fearful of the rest of the partners in the health care system?

Dr. Kenneth Schneider: Gary, did you want to—

Dr. Gary Ing: Yes, if I may. I think a lesson like this—as painful as it is right now, we need to concentrate and focus on how we can do things differently. One is definitely to address this particular quality assurance practice of this particular area. But we need to take the same principles, same strategies, to look at the other areas, the other programs, in the hospital. We need to look at those. Those basic principles are going to be the same in terms of how we're going to manage a quality

practice program. You apply those principles to other programs.

You get your physician leaders and your administrators involved, because they're the ones who are close to the action. They can tell us if there are any flaws, any concerns about the processes we've put in place, and how we're going to monitor and measure those.

Your description about the services outside of the hospital—I'm also in a private practice, so I have a lot of different diagnosing and imaging facilities in the community. But one control we have is we deal with them under the assumption that they have professionalism and they pass all the quality testing. But when you deal with them on a one-to-one basis after months or years, you somehow know the quality of the report and the testing. You have some control over how you're going to manage that. But in a hospital—actually, in a hospital, you have more control because you have different experts there.

The question is, how do you do this? It's the awareness, learning from the mistake that came about, and then you diligently work toward a goal to make sure that you don't have this happen again, or you mitigate any kind of potential risk.

The Chair (Mr. Ernie Hardeman): Thank you very much. We have another short question from the Liberal side.

Ms. Helena Jaczek: Thank you, Chair. Just a very basic question to the CEO, Mr. Musyj: Are you confident in the safety of the drug supply at Windsor Regional Hospital?

Mr. David Musyj: Yes, we are confident. This made us, clearly, take a step back, but we did look at it. At least now it is an isolated—a very isolated—tragic incident that affected a considerable amount of individuals. But as it stands now, yes, I have confidence in not only the system of drugs but also the individuals in the hospital, my team. I have the utmost trust in them.

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Ms. Helena Jaczek: And very quickly: In terms of the 290 patients, what progress are you making—either to you or to Dr. Schneider—in terms of them getting to see their oncologist? Where are we at with that?

Dr. Kenneth Schneider: We've done very well, actually, because we came out fairly quickly with communication to those patients. We've had direct contact with all of them to set up an appointment with their oncologist. A good proportion have already been seen or have attended town halls, and we'll work through the remainder with specific appointments at their request. So we've actually done quite well.

Ms. Helena Jaczek: So what's the outside date?

Mr. David Musyj: Basically, everybody who wanted to see their oncologist has seen their oncologist. Everybody who wanted to wait for their next regularly scheduled appointment is waiting.

Again, that's the insight into the cancer patients. You learn something in health care every day. When they were first contacted by letter and by phone, 50% of them, approximately, said, "I'll wait for my next appointment,

because I know there are individuals who need to see their oncologist sooner rather than later. I'll wait." That's an amazing insight that makes you pause, because of what they're going through personally, that they would reflect and say, "You know what? There are other people in the system who need to see someone sooner."

All 290 patients and families—because unfortunately, 20 have passed since the start of the treatment—have had an opportunity to meet with their oncologist, have either met with them or they're just waiting for their next appointment. Some came to town halls, but I'm very proud of the team who, within a very short period of time, have been able to make direct contact with all 290.

Ms. Helena Jaczek: Thank you very much.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation this afternoon and taking time to come and talk to us. We very much appreciate it. I'm sure it will be of great assistance to the committee as we move forward with this process. So thank you again for coming.

Mr. David Musy: Thank you, Mr. Chair. Thank you, committee.

MINISTRY OF HEALTH AND LONG-TERM CARE

The Chair (Mr. Ernie Hardeman): Our next delegation is from the Ministry of Health and Long-Term Care: Catherine Brown, assistant deputy minister of health systems accountability and performance. I do believe Catherine was here not too long ago. I believe she was here last week, and I was somewhat going to mention it to her and sympathize with her, because I don't believe many questions were to her in the last panel. In order to be here, she was sworn in, so she doesn't have to do that again today. I just remind her that she is under oath still today.

With that, we thank you very much for coming back. You will have 20 minutes to make your presentation. It's here to be passed out. At the conclusion of the presentation, we will have questions as we had before. We will start with the government side the next time.

I will remind everyone that I didn't realize I had originally started with 20 minutes for each one. But, in fact, if you want to cut it in half, you have every right to do that, and then we will come back to you. I just want to point out, that's more work for the Clerk to have to keep track of the time that's left. We don't have the House clock here to do that. We do appreciate that, but I do want to say that, because people may want to, in fact—rather than splitting it into 20 minutes, you can make the circle and do that next time around for better planning purposes. I apologize to the opposition side. I let them go collectively in the same 20 minutes. But we will stick with the rotation, if you want to leave your time for the second time around.

With that, the presentation or the time is yours now, and we'll turn the floor over to you. Again, thank you very much for being here.

Ms. Catherine Brown: Thank you, Mr. Chair. Good afternoon. My name is Catherine Brown. I'm the assistant deputy minister of the health system accountability and performance division with the Ministry of Health and Long-Term Care. I want to thank you all for being here today.

I'll be telling you today about this ministry's response to the recent situation involving certain cancer drugs in some hospitals, and my role in coordinating that response. I am going to need to set some context about oversight and jurisdiction as I do that. I will also bring you up to speed on important developments over the past few days. After that, I will be pleased to take any questions you may have.

Before I get into that, however, I need to express my sincere concerns for the patients who have been affected by this and for the families who were affected along with them. I am not alone in having spoken these words before this committee, but they cannot be spoken often enough. Something has happened here that should not have, and our job in this room and across the health system is to make sure that it cannot happen again.

My role within the ministry is as follows: I have oversight responsibilities for certain areas of the health care system. For example, I oversee the licensing, inspection and reporting regime enforcing the Long-Term Care Homes Act and its regulations, and the Healing Arts Radiation Protection Act and regulations. This includes setting strategic direction for funding and financial policies for long-term care and other health sectors. I should note that this is the only area of my division where we do actual on-site inspections, where we have inspectors who go out and look at sites, both in radiation and in long-term care.

I also provide oversight in support of the implementation of major new health system strategies and reforms, including the wait times and access-to-care strategy. Our goal is to improve existing programs, with an emphasis on best practices, access to services, and ensuring system accountability.

The division I oversee also works collaboratively with the other divisions in the ministry and in very close partnership with the LHINs, the local health integration networks, to ensure that the obligations of the Local Health System Integration Act and related legislation are met. We work together to improve access to care and health care service delivery while ensuring accountability and performance requirements are met.

With respect to hospitals, Ontario's public hospitals are not-for-profit, community-based corporations. They have their own boards and governance structure. They are subject to a number of pieces of legislation. The sort of key ones, or some of the highest-level ones, are the Public Hospitals Act, the Local Health System Integration Act, which I mentioned earlier, the Broader Public Sector Accountability Act, and the Excellent Care for All Act.

Without getting too deeply into the specifics regarding all of those, what that all means is that I, in my role

within the ministry, work jointly with our LHINs in providing oversight in support of Ontario's hospitals. My oversight does not include drugs and pharmacies, but I work closely with my colleagues at Ontario Public Drug Programs, which oversees the province's publicly funded drug programs, and with Health Human Resources Strategy division, which oversees the regulatory system for health professionals, which includes the Ontario College of Pharmacists. The college regulates, as you heard last Tuesday, and accredits community pharmacies under the Drug and Pharmacies Regulation Act and regulates the work done by pharmacists and pharmacy technicians in Ontario under the Pharmacy Act.

The final slice of the legislative oversight pie, if you will, is Health Canada, which regulates the manufacture, packaging, labelling and sale of drugs, and also licenses drug manufacturers, all under the federal Food and Drugs Act. This act also provides Health Canada with broad inspection powers in connection with places where drugs are manufactured, prepared, packaged or stored.

That is a snapshot of the oversight structure that was in place in late March, when it was discovered that there was a problem with certain bags of chemotherapy solution in some hospitals. Those bags contained a lower concentration of medication than should have been there—they were diluted—and patients, as a result, had been underdosed.

As you heard last week from Cancer Care Ontario CEO Michael Sherar, the four hospitals in question immediately stopped using those diluted products—and you've heard more on that today from Windsor—and took the necessary steps to ensure they were taken out of circulation and that proper doses were being administered. They then notified CCO, which in turn notified the ministry. I will point out that those steps seem sequential, but everything was pretty much happening all at once, if I can point it out that way.

At the same time, the priority was to identify and contact those patients who had been affected by the use of these products. Notification was done at the hospital level. It is my understanding that all patients or their families have now been contacted, and most have been able to meet with their hospital and oncologists to understand what has taken place. As Mr. Musyj just pointed out, we have also heard from our hospitals that where meetings have not taken place, it's because patients have deferred the meeting to deal with other things, vacations or otherwise; it is not as a result of not having access to someone to meet with.

Upon learning of the situation, Cancer Care Ontario worked with the province's hospitals to ensure that quality assurance processes are in place for all drugs purchased externally or prepared in hospital.

The ministry, meanwhile, struck a working group on April 8 to coordinate the response to this issue. The group, which I am chairing, includes our partners from Health Canada, the Ontario Hospital Association, the Ontario College of Pharmacists, Cancer Care Ontario, the province of New Brunswick, and the four hospitals, along with other ministry representatives.

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We have a full teleconference meeting every day, and we have since April 8. With the exception of day 1, when New Brunswick was not able to participate, we have had full participation on every call. In addition, we hold bilateral meetings whenever they are needed, and that has turned out to be almost every day. We regularly have separate meetings with Health Canada, the hospitals and Cancer Care Ontario as needed, and it's almost daily that we have been having those meetings.

I can say from where I sit that, except for the fact that this incident happened, the system has pulled together and responded with a view to restoring patient care and safety. The four hospitals—London Health Sciences Centre, Windsor Regional, Lakeridge Health and Peterborough Regional Health Centre—moved swiftly and collaboratively to safeguard the care of all their patients. Patients and families were notified. And on April 11, Cancer Care Ontario was able to confirm that all 77 hospitals in Ontario that provide cancer treatment have verified the safety and integrity of their chemotherapy drugs.

With those critical early steps taken care of, the ministry undertook to examine the supply chain that is in place in Ontario and to properly investigate and understand what had happened here, so that we can ensure that it does not happen again.

To that end, as you know, Dr. Jake Thiessen was appointed as an inspector under the provisions of the Public Hospitals Act to lead an independent review to determine how this incident occurred, and provide recommendations to prevent future incidents. He is being supported in this undertaking by the working group.

It is the intention of the Minister of Health and Long-Term Care that Dr. Thiessen's findings will be made public. We are not going to pre-judge them. Until we see Dr. Thiessen's report, we are going to assume that there is much that we don't know.

One thing we do know is that this happened. It boils down to the fact that instead of overlapping, as jurisdictions so often do, the oversight activities of Health Canada federally and the Ontario College of Pharmacists provincially actually fell short of one another. Referring back to the oversight structure I laid out for you earlier, the province, through the Ontario College of Pharmacists, regulates pharmacies and pharmacists—those are the pharmacies within hospitals and in the community. Health Canada has a responsibility for manufacturers. Marchese, the company that mixed and supplied these drugs to the hospitals, fell into a gap between them. They were producing these drugs in a facility that was neither a pharmacy nor licensed as a manufacturer. It was a grey area, and consequently, there was no active oversight.

The province of Ontario is working to eliminate that grey area. On Friday, the province wrote to businesses that it knows of which might possibly be selling compounded drugs to obtain more information about their processes and oversight. As well, on Friday the Minister of Health and Long-Term Care sent a letter to every

hospital in the province asking them to affirm that they have thoroughly reviewed their medication management processes relating to compounding drugs, both onsite and offsite, so that we may assure Ontarians that necessary safeguards are in place. Responses from hospitals are required by April 26. I will note that the letter went out on Friday and that we have heard from a number of hospitals already, that that assurance has been given that their products are safe.

Also on Friday, the government announced that it is proposing a new regulation under the Public Hospitals Act to ensure that hospitals only purchase drugs from accredited, licensed or otherwise approved suppliers. That regulation has been posted for consultation. In addition, we are working with the Ontario College of Pharmacists on a regulation that would give the college the power to inspect any premises where pharmacists and pharmacy technicians are preparing drugs. I know you heard from the college last week that they have been looking hard at the work of pharmacies and pharmacists in this province with an eye to tightening up the system. They have now confirmed that a proposed regulation is in the final stages of development.

Federally, Health Canada has also acted. As you may know, we are convinced that the lead in all of this must be taken by Health Canada, given that this is a problem that has already occurred in more than one province. On Friday, Health Canada responded to that and announced that it is providing direction to organizations involved in the compounding and admixing of medications. Under this direction, companies must either operate inside a hospital, be supervised by a provincially registered pharmacist, or must hold a federal drug manufacturing license.

These are preliminary measures. “Stabilizing solution” is the term that Health Canada used about their framework. For our part, we have taken some measures and look forward to see what Dr. Thiessen concludes and what suggestions he may offer. Until we know these things, we are inclined to view everything being done right now as preliminary but necessary.

Once we have those suggestions, we look forward to continuing to work closely and diligently with Health Canada, Cancer Care Ontario, the College of Pharmacists and our hospitals, as well as with our colleagues in other provinces, to ensure that the supply chain of drugs on which patients in this province and this country depend is as safe as it can possibly be. It is the view of this ministry that no other response to recent events is acceptable. As I have said previously, this cannot happen again.

I will be happy to take your questions.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. With that, we will go to Dr. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Thank you, Ms. Brown. Your presentation is very comprehensive, and I know you were trying to get through it all. I’d like to sort of recap, with perhaps just a little more detail in some areas of what you’ve had the chance to tell us.

First of all, when did you personally hear of this incident?

Ms. Catherine Brown: I was on vacation, out of the country, the week that this began, and I was notified while I was on vacation. Then I returned to the country on the 6th of April. I was briefed on Sunday, on the 7th, and began working on it first thing on the 8th.

Ms. Helena Jaczek: Right. And you’ve basically been the lead in terms of looking at responses in terms of what the ministry might be able to put forward to address this grey area.

Ms. Catherine Brown: That is correct.

Ms. Helena Jaczek: As we heard last week—clearly from what we heard, the College of Pharmacists acknowledges that other provinces do have different provisions in terms of their mandate and so on. Could you just zero in on what we’re lacking here in Ontario?

Ms. Catherine Brown: The way in which the system is structured in Ontario is that the college has oversight for pharmacists where they practise in community pharmacies, and of course hospital pharmacies are under the jurisdiction of hospitals. Their pharmacists are regulated by the college as well. In Ontario, drug manufacturing, as is the case in the rest of the country, is overseen by Health Canada under the Food and Drugs Act, as I noted.

As the folks from Windsor spoke to, this grey area was not known to us in this way until this happened. How this company is operating outside of that is still not clear to us, and that’s why we have these investigations in place.

Ms. Helena Jaczek: You made reference to appointing a third-party expert reviewer. Can you just describe again, in a little more detail, the exact mandate that Dr. Thiessen has?

Ms. Catherine Brown: I can. Dr. Thiessen was appointed under the Public Hospitals Act. He has jurisdiction to go in and look at the four hospitals, and he has jurisdiction to ask anyone else to speak to him about the events that took place here and to look at the procurement chain, if I can say that, and all of the steps along the way, from the contract through to the delivery of chemotherapy, to try and determine where things went wrong.

To my understanding, thus far, he has met with the four hospitals and has asked to meet with others and will continue to meet with others who have been part of this, including Health Canada. I believe he’s asked for a meeting with Marchese and others.

Ms. Helena Jaczek: Is a possible outcome that he will make a recommendation related to oversight by the College of Pharmacists in Ontario?

Ms. Catherine Brown: He can make whatever recommendation he sees as appropriate to try and determine a better way to do this.

Ms. Helena Jaczek: And, as you’ve told us, this review will be made public.

Ms. Catherine Brown: Yes.

Ms. Helena Jaczek: Again, the working group—this is the group that you chair: I think you may have alluded

to it, but could you just tell us again who exactly is on that group, why they were chosen?

Ms. Catherine Brown: The group represents everyone that has a piece of this pie, so Health Canada, our partners in oversight; the four hospitals that were involved; the Ontario Hospital Association as it relates to the other hospitals in the system; the College of Pharmacists, of course; my colleagues within the ministry who have related responsibilities, as I noted—drug programs and health human resources. I'm missing somebody. Cancer Care Ontario; I'm sorry. Cancer Care Ontario is a key partner in the delivery of cancer services across this province; 60% of cancer services are delivered by Cancer Care Ontario, so they are part of that group as well.

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Ms. Helena Jaczek: Could you describe the relationship, if there is one, between the Ministry of Health and Long-Term Care and Medbuy?

Ms. Catherine Brown: As far as I'm aware, we don't have a direct relationship. Medbuy is a shared service procurement entity. They have contracts that—they offer services to procure on behalf of parties in the health care system, on behalf of hospitals or others. They undertake those activities on their behalf.

Ms. Helena Jaczek: So it really is up to hospitals to make a decision whether they wish to procure product through Medbuy?

Ms. Catherine Brown: That's correct.

Ms. Helena Jaczek: How would you see hospitals to be guided in this procurement practice? We heard reference to Ministry of Finance guidelines and so on. Perhaps from the perspective of the Ministry of Health and Long-Term Care, what would you feel would be appropriate in terms of hospitals safeguarding the safety of the drug supply?

Ms. Catherine Brown: Hospitals are independent corporations. They have their own board of directors, and they have their own accountability and governance for the operations of that entity. They are responsible to ensure that the people with whom they do business are appropriate. Medbuy is one of many shared service procurement organizations through whom people in the health care system procure.

We also provide guidance to the hospitals through the Broader Public Sector Accountability Act, through the broader public sector procurement directive and the rules and guidelines therein about ensuring that there is balance between quality and ensuring that they take the necessary steps to ensure that the products and services that they're procuring are appropriate, and that they are safe and there is quality.

Ms. Helena Jaczek: Mr. Musy made reference to the quality improvement plan that each hospital must provide, I presume, to the LHIN. Could you just talk a little bit about where that falls into the picture here?

Ms. Catherine Brown: Quality improvement plans are part of the Excellent Care for All Act. These are plans that the hospitals undertake to improve a variety of things under their jurisdiction, including the delivery of service.

Ms. Helena Jaczek: And these quality improvement plans are forwarded to the LHIN or—

Ms. Catherine Brown: They are provided to the LHIN, yes. The LHIN has an agreement with all of its health service providers, and the primary relationship is between the LHIN and the hospital, although the ministry is party to all of those in some way.

Ms. Helena Jaczek: And if the LHIN should be concerned about a particular facility, would the ministry be so informed?

Ms. Catherine Brown: Typically, yes.

Ms. Helena Jaczek: Now, going back to your presentation, you talked about how the government is "proposing a new regulation under the Public Hospitals Act to ensure that hospitals only purchase drugs from accredited, licensed or otherwise approved suppliers." Could you go into more detail and give us some examples of what an accredited, licensed or otherwise approved supplier might look like?

Ms. Catherine Brown: That would include any manufacturer that is licensed under the Food and Drugs Act; any accredited pharmacy under the Ontario Drug and Pharmacies Regulation Act—a corporation that procures products on behalf of a hospital would have to do that in the same way, so it also captures those entities like Medbuy that you just noted; a wholesaler who has bought the drug from a related entity; a specified person inspected by the College of Pharmacists that is not a pharmacy, so an independent pharmacist; another hospital—should they be procuring from another hospital they would need to ensure that those assurances were in place; through another government, both provincially or the Canadian government; an accredited pharmacy in another jurisdiction, as I noted; or a person conducting a clinical trial.

Ms. Helena Jaczek: So essentially, each of those entities you've described from which a hospital could acquire a drug is inspected in some fashion by an entity or Health Canada.

Ms. Catherine Brown: It is regulated in some fashion by one jurisdiction or another, yes—either by Health Canada or by the province in which it resides.

Ms. Helena Jaczek: Again, a little more detail on what Health Canada has proposed—in your presentation, you mentioned that Health Canada "is providing direction to organizations involved in the compounding and admixing of medications." So this would include Marchese itself, Baxter and so on. If you could, again, detail a little bit exactly what that means. What is this direction?

Ms. Catherine Brown: I will say that this is something that Health Canada introduced on Friday and I haven't seen all of the details myself. We understand that their framework would require companies to either operate within a hospital, as many pharmacies do; be supervised by a provincially registered pharmacist, so that would include all of our community pharmacies, for example; or must hold a federal drug manufacturing licence. So they must find themselves within one of those

categories. That is my understanding of the direction. They will be forthcoming with more detail at some point in the near future is my understanding.

Ms. Helena Jaczek: So you feel confident that between the Health Canada announcement on Friday and the proposed regulation that our government has proposed, we would have a safe and secure supply of drugs entering hospitals. Would that be true?

Ms. Catherine Brown: I would believe that those are two steps—two or three; there are several that I've noted—that will take us closer to that. I think until we hear from Dr. Thiessen and what he finds—I would want to be sure that we are responding to what his findings might be, if there is something else that we need to do additionally to ensure that that safety is fully in place.

Ms. Helena Jaczek: I'll save the rest of my time. How much is it, by the way?

The Chair (Mr. Ernie Hardeman): You have about seven minutes left.

Ms. Helena Jaczek: Okay, we'll save that for later.

The Chair (Mr. Ernie Hardeman): The official opposition? Whoever wants to go first.

Mrs. Christine Elliott: I'll start, then. Thank you very much for joining us again, Ms. Brown.

The representatives from Windsor who were just here said that it wasn't really a big problem to change the decision with respect to ordering premixed solutions. This was something that was sort of up to them to decide. I was wondering if you had any guidelines that the ministry issued in this respect or any procedure that needed to be followed in order to make these sorts of decisions within the hospitals.

Ms. Catherine Brown: It is within the hospital's jurisdiction, as you noted, to make those determinations. They are independent corporations. They need to look at how and where they are procuring and ensure that they are doing the best they can to ensure those procurements are safe.

We do not issue particular guidelines around procuring compounded drugs. We issue guidelines around procurements more generally and ensure that those procurements meet a number of criteria. Cancer Care Ontario also issues guidelines around the use of compounded drugs and the labeling of compounded drugs. So there are a number of people or players who have a role in this to provide guidance.

Mrs. Christine Elliott: Is this a trend that's happening, that you're seeing this sort of outsourcing happening? Has it been happening with other drugs through the years or is this something that's just more recent?

Ms. Catherine Brown: No, I think as Windsor pointed out—and I am learning about this over the last many weeks as well—hospitals have been undertaking this work for many, many years, and those hospitals that have a large volume of certain drugs or solutions to be provided have undertaken this for quite some time.

Mrs. Christine Elliott: Are they required to submit reports to you at all or is this something that they just deal with internally within the hospitals?

Ms. Catherine Brown: They submit a variety of reports to us but they don't need to submit reports about every procurement. They need to submit reports ensuring that their procurements comply with the rules of the province, but we don't ask for—to my knowledge, anyway—the particular details of every single procurement. Again, that is up to the hospital. They have a board. They need to assure their board that those procurements are in keeping with the rules of the province, and then they attest to that to the province under the Broader Public Sector Accountability Act.

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Mrs. Christine Elliott: But this would have been something that the ministry would have been aware of, that there were a number of hospitals that were ordering premixed solutions for certain kinds of medications?

Ms. Catherine Brown: The ministry is aware that hospitals procure from other hospitals, third parties, manufacturers. We're aware of that. I'm not sure what knowledge the ministry would or wouldn't have had about this particular procurement.

Mrs. Christine Elliott: Was there ever any discussion, I guess, within your department that you're aware of with respect to this trend, or any discussion, anybody reviewing it, any concerns being issued with respect to it?

Ms. Catherine Brown: There was no discussion that I'm aware of in my division about this, as you describe it, trend. I think this is something that has been going on for many years. I think as Windsor noted in their remarks, this grey area, however it came about—we don't know if this was something where a manufacturer was working around existing rules or if this was just a gap in oversight, but this was not something that had been discussed within my division previously, no.

Mrs. Christine Elliott: All right. Thank you. My colleagues may have some questions.

The Chair (Mr. Ernie Hardeman): We'll make the full circle, so we'll go to Ms. Gélinas.

M^{me} France Gélinas: Jeff, you're not going? I think Jeff wanted to go.

Mr. Jeff Yurek: How many minutes have I got in my time?

The Chair (Mr. Ernie Hardeman): He wasn't here when I explained that we would circle when one was finished, and then the time could be used. But it's fine—

Mr. Jeff Yurek: It's going to be the same question, either way.

The Chair (Mr. Ernie Hardeman): —if we want Mr. Yurek to go first. Mr. Yurek?

M^{me} France Gélinas: Go ahead.

Mr. Jeff Yurek: Thanks, Chair.

Thanks for coming in today. I noticed—and I'll read it out here. It's in your presentation: "The government announced that it is proposing new regulations under the Public Hospitals Act to ensure that hospitals only purchase drugs from accredited, licensed or otherwise approved suppliers."

To me, I would have assumed that would have already been in place. If you went out and polled anybody on the

streets, I bet you'd probably think, "Yeah, my hospital does buy from an accredited, licensed or approved supplier." That's common sense. And yet the government didn't have that in place for procurement. Your thoughts on that? I mean, that's a glaring, glaring error.

Ms. Catherine Brown: I think that the province had and the hospitals have very solid procurement rules and they follow them very closely. I think it's unfortunate that we find ourselves having to write a rule like this to ensure that hospitals are looking at those entities and ensuring that they are regulated.

As Windsor pointed out and as has been raised previously with this table, this area of oversight and lack of oversight was not something that any of us understood to exist in this way, and I think that the hospitals themselves were—I can't predetermine what Dr. Thiessen may find, but it is my understanding the hospitals weren't aware that this entity was outside of jurisdiction. I'm not sure how we will find that that happened. So yes, it is unfortunate that we find ourselves having to write such prescriptive rules to remind everyone and to give them the ability to check the credentials of anyone from whom they are purchasing these products.

Mr. Jeff Yurek: So in terms of the hospitals, you treat them as independent businesses, even though it's public health care and you guys are actually in charge of them, the Ministry of Health.

Ms. Catherine Brown: No, I didn't say that. I said that they are independent corporations. They have their own boards, but they are accountable to the province and to the LHINs and to us and to the taxpayer under a variety of pieces of legislation. But they do have their own boards to whom they are also accountable for the operations of those entities, like many, many health care entities across the province.

Mr. Jeff Yurek: So they're accountable to the Ministry of Health and you guys set standards and policies for them to achieve in order to ensure that they're reaching a certain benchmark?

Ms. Catherine Brown: In many areas, yes.

Mr. Jeff Yurek: Except in the procurement of—

Ms. Catherine Brown: No, we have rules on procurement under the Broader Public Sector Accountability Act. There are rules and guidelines on procurement and, as I indicated, they're required to sign an attestation every year indicating that they have operated within those rules.

Mr. Jeff Yurek: So when the hospital has the procurement, and with regards to Medbuy and other third party outsourcing companies that would purchase on their behalf, do you have any policy as to how they enter into an agreement with a company like Medbuy or any other ones out there, or is that left up to their devices?

Ms. Catherine Brown: The policies around procuring from a second party or a third party would be the same policies around how they procure. They are required to procure in the same way, ensuring quality and all of those other aspects around a procurement.

Mr. Jeff Yurek: Okay. I'm good.

The Chair (Mr. Ernie Hardeman): Okay. France Gélinas.

M^{me} France Gélinas: We just had a number of representatives from the Windsor hospital come and talk to us, and it became clear from their opening remarks and from the answers to our questions that as players in the hospital and in the cancer system, they interact with an awful lot of partners. They take it for granted that all of those partners that are part of our health care system are regulated, that they have oversight, that they can be trusted to be regulated, to have oversight. Basically, this is how they can do their work, because they're never going to do it all. There's always a part that is done elsewhere, whether a lab test or an X-ray, a cardiogram or whatever, but they trust that either the independent health facilities or the multiple areas that make up our health care system have oversight.

You head the health system accountability and performance division. How long have you been the ADM for that division?

Ms. Catherine Brown: Since September of last year.

M^{me} France Gélinas: Okay, and how long has this division been there?

Ms. Catherine Brown: I'm going to say seven years, eight years.

M^{me} France Gélinas: Okay. So, basically, when the Ministry of Health changed its focus to be more of a steward, it put this new health system accountability and performance division in place to do the oversight of their health care system, and you happen to be the ADM of this. The questions that are at the core of this are: How could it be that a part as important as procuring drugs was operating without any oversight? How could it be that we had that grey area and that after seven years of having an ADM—not you but people before you—of health system accountability, nobody had noticed that there was a grey area?

Ms. Catherine Brown: I will just comment: It was not operating without oversight. We understood in Ontario that the areas that produced pharmaceutical products, such as manufacturers, were fully under the jurisdiction of Health Canada. Health Canada believed that their manufacturing oversight was intact.

We further believe that in Ontario's jurisdiction we had fully covered off pharmacies in the community and in hospitals and had full jurisdiction over pharmacists in the province. That this area exists is something that, as you point out, was not known to us, and how it came to be, we're still unclear on. Whether any of these entities are operating completely outside of oversight—it would appear this one was. How they came to be doing this is unclear to us.

As I mentioned in my remarks, we have asked those entities that we know that do similar work to this to provide for us information about how they are operating. Health Canada is aware that we have undertaken to send those letters. At the same time, Health Canada is asking those entities that are providing compounded solutions to let them know that they're operating under provincial

jurisdiction or federal jurisdiction, so that we can shine a light on those who are operating between the rules, if I can say it that way. How they came to be between the rules may be something they have chosen to do, or it may in fact be a gap that arose in a way that none of us anticipated.

M^{me} France Gélinas: We've all now been following the series of documents that have been put forward by Health Canada. Since 1997, they have talked—and I would say even warned—of a grey area of oversight, specifically between the manufacturing and the compounding of drugs. Those have been shared with the provincial government. I didn't see the one that's dated 1997, but we saw 2001 on. For the last 12 years, we know that there's a grey area of oversight, and nobody does anything. How come?

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Ms. Catherine Brown: It is my understanding that Health Canada has been looking at this issue for some time. The provinces have responded to Health Canada in that regard. It is very clear what the province's jurisdiction is in this in regard to pharmacies and pharmacists. This is not a pharmacy. It's not a pharmacy by the rules of any province. It is some form of manufacturing. And as you pointed out, I believe, last week, looking at the federal policy, it identifies that where it falls outside of provincial jurisdiction, it is within federal jurisdiction.

M^{me} France Gélinas: And vice versa. So here we are for 12 years, maybe longer—we could even say for 15 years, since it was identified in 1997. We know that there's a grey area, but yet no action. Then, from the time you come back on April 7 to last Friday—so in 10 days—we are able to put oversight, change directives to the hospital and basically be very proactive on a file. Within 10 days, we were able to do all of this, yet within 15 years we did nothing. I'm having a really tough time with that. It seems that the steps that you have put forward were not very difficult. You could have taken them, frankly, years ago.

Ms. Catherine Brown: The rules that the province has put in place, as Mr. Yurek pointed out, are to prevent hospitals from procuring from an entity that is in the grey zone. Health Canada has stepped up to issue a directive to require entities like this, under their federal law—the province has taken every step it can under the jurisdiction it currently has to oversee pharmacists and pharmacies in Ontario. As I mentioned previously, this is not a pharmacy. It is a type of manufacturer, and Health Canada has moved forward in the last week to undertake this direction that it has provided on Friday.

We have indeed taken a number of steps over the last two weeks in response to what we can do within Ontario to prevent this from happening again.

M^{me} France Gélinas: All right. So we know for a number of years that there's a grey area. We also know that all that the government of Ontario, the Ministry of Health, has to do is issue—what have you called it?—a proposed new regulation that hospitals only purchase drugs from accredited, licensed or otherwise approved

suppliers. Had we done this when the grey area was identified, I think that there's a lot of hardship that would have been avoided. Do you agree?

Ms. Catherine Brown: I can't comment on what hypothetically might have happened if we had done this. As I mentioned and as I mentioned in response to Mr. Yurek's question, I think it is very unfortunate that we find ourselves here. As Windsor pointed out, none of us anticipated that anybody would be trying to work around the rules. We did what we needed to do when this situation arose. We took every step possible within our jurisdiction to respond to this and to ensure patients were safe and to ensure that this is prevented going forward, and we will continue to do that when we hear from Dr. Thiessen what has caused this incident to arise.

M^{me} France Gélinas: But isn't it your job to think forward that things like this could happen? We know there's a grey area. You hadn't anticipated that they would do something like this, but the precautionary principle—how much harm would there have been to say, "We've identified a grey area. Just to make sure that nothing derails, we will make sure that when you procure drugs and you have this fancy little language here, you only purchase drugs from accredited, licensed or approved suppliers?"

It worries me that if you haven't been any more proactive in this, what happens to other programs and services that used to be in hospitals that are now being more and more provided in the community? Isn't it your job to be proactive?

Ms. Catherine Brown: It is our job to do our best to be as proactive as possible, and yes, there are things that we do every single day to try and look forward and look around those corners to anticipate this type of thing. As Windsor pointed out, it has shone a light on this kind of area. We are looking to be sure that there isn't anything else like this that we hadn't anticipated that may cause a problem. We are doing everything that we can within our jurisdiction to try and ensure that this doesn't happen again.

I will say that we don't know that the—the lack of oversight is a lack of oversight. We still don't know what caused this problem. We don't know that the lack of oversight is what caused this problem in the system. Dr. Thiessen's work is looking all of the steps in the procurement, in the way in which the procurement was worded and the way in which the instructions to prepare the products were undertaken. It may be that it was as a result of the oversight; it may be that it was not. Regardless, we are taking steps to ensure that we change the way in which those procurements are undertaken and ensure that companies that operate outside of the rules are not part of the procurement chain in Ontario.

M^{me} France Gélinas: There are many other parts of our health care system—as hospitals divest themselves and concentrate on their core mandate of providing acute hospital care, every other program and service that used to be done in the hospital, more and more are being done in the community and more and more are being done by

unregulated—is this an alarm bell for you that you will get really active in your role at health systems accountability to make sure that we build regulations for all of this community side that is unregulated?

Ms. Catherine Brown: I'm not sure of the pieces of the system that you're referring to that are unregulated. As part of my role, we look at ensuring that the professionals that provide health services to people across Ontario are regulated, that they are abiding by rules that are set out by their professional associations or otherwise, that we ensure that there is oversight, that where we have inspection capacity, we utilize that, or, where a college is regulating those professions, that they are ensuring that those professionals are undertaking their responsibilities in accordance with their rules.

M^{me} France Gélinas: They do, and they do that well. Once a regulation process is in place, I think it has served us well, but the question remains: How come you don't know what part of the system is not regulated? Shouldn't you know that? Would you like me to rhyme some off for you?

Ms. Catherine Brown: No, I didn't say I don't know what part of the system is unregulated. I said I wasn't sure what part of the system you were referring to that was unregulated.

M^{me} France Gélinas: Okay. So my question then: Do you know what other parts of the system are not regulated?

Ms. Catherine Brown: We work very closely with all of our health service providers, all of the entities that we fund through the LHINs or directly, to ensure that they have guidance over the services they are provided, either through their respective regulatory bodies or otherwise, to ensure that there is accountability in the system for all health service providers at every level.

M^{me} France Gélinas: But you know that there are services out there that are unregulated?

Ms. Catherine Brown: I'm trying to think what service you would be referring to. Perhaps you could tell me what one you're referring to.

M^{me} France Gélinas: Let's start with palliative care homes. What kind of regulation does the ministry have over palliative care homes?

Ms. Catherine Brown: The professionals that operate within a palliative care home would be guided by the rules of their profession, and—

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M^{me} France Gélinas: But the home as a whole?

Ms. Catherine Brown: Palliative care residences are funded by the LHINs, and we look at the care plans that they provide and the services that they provide. They are part of the health care system. They have health service providers within their four walls who are regulated, and they have other service providers, like cleaners and cooks who are not necessarily regulated health professionals.

M^{me} France Gélinas: I could tell you more. Like, patient transport is supposed to have regulations for inter-facility patient transport. They're still unregulated. They're still operating out there. I'm not interested in

going there. I'm more interested in—I'm disappointed that after what has just happened, there is great interest in one particular area, the supply chain of chemo drugs because that particular area derails because there was no oversight, because it was not regulated. But then it doesn't seem to have sparked any kind of a willingness to look at other parts of the health care system that are in exactly the same situation as what we had. They may not be supplying chemo drugs to our cancer patients, but they are still in the same situation as what brought us here.

I sort of thought that with a title such as health system accountability and performance division, you would keep an eye on those things and say, "Well, here's a call to arms, to really go forward and regulate part of the health system," especially as, as more and more hospitals divest themselves of programs and services going into the community, oversight of the divestment is not happening. You are in charge of this. Why isn't it happening?

Ms. Catherine Brown: It is not to say it is not happening. Respectfully, we have spent the last several weeks focused very hard on this issue to ensure that we are taking every step possible, that the hospitals are taking every step possible, that we are ensuring that our partners at Health Canada are doing their part to address this issue that is before us. We look across the rest of the health care system on a regular basis, and continue to do so, to ensure that appropriate accountabilities are in place for all types of service provision. To say that we have not done that over the last several weeks is somewhat incorrect. We continue to look always for where we can apply greater accountability across the system. My focus, and the focus of key people on my team, in the last three weeks has been on this issue and making sure that we are doing everything we can to support the hospitals, the patients who were impacted, and making sure that we bring this problem to ground very quickly and put the rules in place that are necessary to prevent it from happening again. It's not to say we're not continuing to look elsewhere across the health care system for where there needs to be greater oversight or accountability. We do that regularly.

M^{me} France Gélinas: So if we find other areas where the federal government identified grey accountability areas, where their oversight ends and yours starts and there is no overlap, are you presently reviewing where those exist?

Ms. Catherine Brown: We are looking at all areas of the—we regularly look at all areas of health care as we go forward.

And to your point that Health Canada identified this issue, Health Canada has been looking at this issue for a number of years to determine where they could take greater action in this area. The provinces have been responding to Health Canada as they are asked to do that, and Health Canada has, as of Friday, taken a step forward in addressing this issue.

M^{me} France Gélinas: I'll save my time.

The Chair (Mr. Ernie Hardeman): Okay. Thank you. Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Ms. Brown, I just want to go through a little bit of your role vis-à-vis the role of your colleagues in the Ontario public drug programs, which oversees the province's publicly funded drug programs, and the health human resource strategy division, which oversees the regulatory system for health professionals. I have my Ministry of Health and Long-Term Care org chart here. I look at it regularly because it's a little confusing. These are two other ADMs.

Ms. Catherine Brown: Yes.

Ms. Helena Jaczek: These are your colleagues and perhaps have more direct oversight. But presumably you could help us a little bit with the College of Pharmacists. Are you aware of, or have any of your colleagues ever brought to your attention, what we heard last week from the relatively new registrar of the Ontario College of Pharmacists, that there was a grey area in terms of lack of oversight by the college in this area? Were you made aware of this?

Ms. Catherine Brown: I was not made aware of this until this, but I am, as I said, relatively new to this portfolio and the area around drug programs is the responsibility of a colleague. The college is an oversight body.

The regulators: To your point, actually, and I should have made this clear earlier, it is the regulators who typically deal with Health Canada most directly on these issues, to your point on having Health Canada having identified it some time ago. The regulators would tell you that they also had identified it to Health Canada some time ago as being outside their jurisdiction for pharmacies and pharmacists, and raising with Health Canada the need for Health Canada to address this issue. I couldn't comment on when the regulator here in Ontario may have or not brought that issue to the attention of anyone in the ministry. I don't know.

Ms. Helena Jaczek: Right, but obviously well aware of it. This regulation that we have proposed will allow the College of Pharmacists to enter into the premise of this particular compounding facility and others like it?

Ms. Catherine Brown: That is our understanding of what the college will be recommending—it is the college that would recommend the regulation—that they would like jurisdiction to be able to go into these types of premises. But they would still have jurisdiction only for—if I can use the word—"sanctioning" those actions of the pharmacists within that entity. They still would not have jurisdiction to shut down that kind of entity because they only have that role over pharmacies or pharmacists, and this is more a manufacturer of sorts, someone who's preparing products and distributing them rather than a pharmacy.

Ms. Helena Jaczek: In other words, if they went into a compounding facility and they found some sort of error, they would be able to have some sort of sanction against the pharmacist, that individual.

Ms. Catherine Brown: Correct, pharmacists or pharmacy technicians. Those are the categories of professionals they oversee.

Ms. Helena Jaczek: In terms of your role, health system accountability and performance, how have you

felt—you're having these daily meetings with the working groups in the hospitals and so on—in terms of the quality assurance measures that hospitals—we heard from Windsor Regional—have in place to ensure the safety of the drug supply within the hospital? What is your analysis of their quality assurance programs?

Ms. Catherine Brown: They have good quality assurance programs in place, both for products that are prepared within their hospitals and also for those that they procure from someone else. I think, as Windsor noted, it was surprising to them that someone from whom they were procuring—that an error had been made, if in fact they had made an error, and that they were outside of a regulated authority.

Ms. Helena Jaczek: Right. Now again, your working group is meeting regularly. Is one of the questions that you've been considering, what other companies are out there like Marchese?

Ms. Catherine Brown: We have talked about that, and talked about that with Dr. Thiessen. As I noted, letters were sent on Friday to entities we know of that might be preparing compounded products for purchase by hospitals or a third party, to ask them under what regulatory authority they are operating, to get a better understanding of that.

Ms. Helena Jaczek: Have you contacted Medbuy at all? They've had requests for proposals and so on. They must have a list of names of companies.

Ms. Catherine Brown: It is one of the vehicles that we use to identify those companies, not necessarily through Medbuy, but to look at the kind of entities that companies like Medbuy—there are many of them—are procuring this type of product from. That is one of the ways we identified the companies that we have gone to.

Ms. Helena Jaczek: Do I have any time left?

The Chair (Mr. Ernie Hardeman): You have about three minutes left.

Ms. Helena Jaczek: I'll save it, just in case.

The Chair (Mr. Ernie Hardeman): The official opposition, Mr. Yurek.

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Mr. Jeff Yurek: Just going back to my question about—you talk about extending the Ontario College of Pharmacists' ability to go in and inspect the premises and not shut down the facility. That's still going to leave a grey area at the end of the day. Just going into my other critic field that I'm in, in auto insurance you see health clinics running that are using health care professionals without them knowing that there's fraudulent activity going on. If there's no deterrent in the system to shut down a manufacturing facility that is not doing the correct things, even though the pharmacists are on duty, or the pharmacy technicians, that's not really going to stop someone who is unscrupulous in the system from using pharmacists or pharmacy technicians to get to their end result. So—

Ms. Catherine Brown: I'm not sure what the question is.

Mr. Jeff Yurek: The question is, therefore, do you think that's enough? I'm seeing a gaping hole right there that's still going to create a grey area. Do you have any thoughts on that?

Ms. Catherine Brown: The rules that—we haven't seen what the college is going to propose in the way of its new regulations or what it would like to see. In my understanding of how I described it, it would still allow Health Canada to go in and say—if we were to say we don't want the pharmacists practising there, or the college was to say that, Health Canada still has authority to go in and shut them down as not being under their regulatory authority, as a manufacturer. So in my understanding that doesn't leave a gap. Health Canada can fill that gap.

Mr. Jeff Yurek: Okay. And have you reviewed what other provinces are doing with regards to procuring medication outside of hospitals?

Ms. Catherine Brown: We have looked at other provinces in this regard, and lots of provinces procure products from outside the hospital. Chemotherapy drugs some provinces procure outside their hospital, less so than Ontario just because of volume, but some of the larger provinces—Alberta, BC—procure from a third party or a second party outside, yes. In fact, as you know, New Brunswick was one of the provinces that procured from Marchese under this contract.

Mr. Jeff Yurek: Procured in Ontario from the company—

Ms. Catherine Brown: They procured the products from Marchese in Ontario, yes, but for use in New Brunswick. So lots of provinces and lots of hospitals undertake this activity on a regular basis.

Mr. Jeff Yurek: Now, do they have oversight or standards at the provincial level overseeing the hospitals?

Ms. Catherine Brown: From the work that we have done over the last number of weeks, it would appear that this particular issue is an issue for all provinces and all provinces were of the same—many provinces; I can't speak for all of them. Many provinces certainly from the conversations that we have had with them were of the same view, that this was under the jurisdiction of the federal government and they were not aware that it was not being, if I can say, covered off.

Mr. Jeff Yurek: Okay. Jane, do you have a question? We'll hold our minutes.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Gélinas.

M^{me} France Gélinas: You have explained to us that Dr. Thiessen is looking and will do a report that will be made public, and he is free to talk to whomever he wants. How are you making sure that whoever wants to talk to him is free to do so?

Ms. Catherine Brown: I'm not sure I understand the question.

M^{me} France Gélinas: I'm looking at whistle-blower protection. I'm looking at people who work within the system who have a story to tell but don't feel that they could come forward without risking their job.

Ms. Catherine Brown: We have certainly made known that anyone can come forward and ask to meet with Dr. Thiessen. We are working with the key people just to set up those appointments. Nothing thus far has come to our attention or to his in that regard—not that I'm aware of. I haven't talked to Dr. Thiessen since late last week, but I'm not aware that he's heard from anyone.

M^{me} France Gélinas: Okay. Are you aware if he reaches out to some of the pharmacy technicians and some of the people who work in the field—

Ms. Catherine Brown: I'm not a party to the discussions that he is having. I know that when he goes to the hospitals, he asks to meet with anyone and everyone who would like to meet with him. I know he has those meetings—has had a number of discussions in the hospitals, but we are not part of those discussions, as it's an independent review.

M^{me} France Gélinas: If you were made aware that there are people who feel threatened, who feel their job would be in jeopardy, if they were to speak and say what they have to say, what kind of assurance can the government and can you offer those people?

Ms. Catherine Brown: We would certainly put them in touch with Dr. Thiessen and allow that conversation to happen. I guess it would depend on where the individuals resided in their organization. Certainly, most labour relations laws allow for that kind of protection, whistle-blowing protection, and protection from reprisal. We would try and offer that same assurance to anyone outside of a union.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes all the time.

The Liberal side?

Ms. Helena Jaczek: Thank you, Chair. As we've said in this committee last week and again, this is an opportunity to learn and to ensure that there aren't any other grey zones. I guess, picking up a little bit on my colleague Ms. Gélinas: As chairing this working group, you've outlined some of the areas you've been looking at. Has it triggered any thoughts of further investigation, not perhaps related directly to this incident but looking more systemically, in your capacity as ADM for health accountability?

Ms. Catherine Brown: We're certainly looking at—absolutely. As I think it was Dr. Ing from Windsor stated, when these things happen, they are terribly unfortunate and difficult for the patients who are impacted. As public servants, it calls upon us to do whatever we can but also to look as hard as we possibly can at other areas within our jurisdiction to be sure that there isn't something else like this. As we've had these discussions, as was mentioned by Mr. Yurek and others, about: What is in the procurement rules? Does there need to be more? Is there anything we should be doing in addition to the work that we've already spoken about today? We continue to look not just at this area but other areas of oversight and accountability with this light on them, if I can say it that way.

Ms. Helena Jaczek: And then, as we've said again, the care of the patients is absolutely paramount—those who have been affected. You're in daily discussion with the hospitals. How are you feeling about the progress being made in that regard?

Ms. Catherine Brown: I think that the hospitals have done an extraordinary job in their work, reaching out to the patients and their families. I know that they have left no stone unturned in ensuring that they reach every single person that has been impacted. We have heard of the extraordinary things that they have done—the very difficult conversations that the oncologists and the hospitals have had; the extraordinary conversations, as was mentioned by Mr. Musyj, where patients have said, “Talk to someone who's in greater need than me. I'm fine for now.”

It has been extraordinary what the hospitals have done in such a short time, as is necessary in this circumstance, and they've really risen to this challenge.

Ms. Helena Jaczek: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes everyone's time.

We thank you very much for coming in this afternoon to help us out with this information meeting. Thank you very much.

A couple of items: As you can tell, there's a bit of a challenge with the timing of the delegations each day, with the time each delegation gets. Between now and the end of the time allotted, there isn't time for another delegation. We'll find the same thing tomorrow when the two hours—you can get two delegates in in two hours. So I would ask the subcommittee if we wanted to meet slightly after—actually, today it would work, but tomorrow it won't. If we'd ask the subcommittee to just stay for an unofficial meeting so we can make a decision of how we deal—either changing the time a little bit for each delegation, or have this time left over—so if the subcommittee would meet after this one.

I also wanted to point out that on your tables are the reports that were asked for in the last meeting. They've all been provided here.

Interjection.

The Chair (Mr. Ernie Hardeman): From Cancer Care Ontario. If they are not sufficient to what you requested, make sure you let us know so we can go after them further.

With that, thank you again. We'll hopefully have a quick meeting with the subcommittee. This meeting stands adjourned.

The committee adjourned at 1630.

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Mardi 23 avril 2013

Standing Committee on Social Policy

Oversight of pharmaceutical
companies

Comité permanent de la politique sociale

La surveillance, le contrôle et la
réglementation des entreprises
pharmaceutiques



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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Tuesday 23 April 2013

Mardi 23 avril 2013

*The committee met at 1601 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIES
LAKERIDGE HEALTH

The Chair (Mr. Ernie Hardeman): I call the Standing Committee on Social Policy to order. We're meeting today to continue a study relating to the oversight in monitoring and regulation of the non-accredited pharmaceutical companies.

This afternoon, we have with us the Lakeridge Health Corp. We want to thank them very much for being here. I guess before we start, we'll ask the Clerk to have you all sworn in. I'm sure there was no doubt about it at all, anyway, but that you will swear it's the truth, the whole truth and nothing but the truth.

With that, we'll turn it over to the Clerk.

The Clerk of the Committee (Mr. William Short): I'll just start on the end of the table.

Ms. Motz; correct?

Ms. Leslie Motz: Correct.

The Clerk of the Committee (Mr. William Short): Did you want to swear an oath or be affirmed? The Bible's there or if you want to be affirmed, just raise your hand, whichever—

Ms. Leslie Motz: No, I'll swear an oath. That's fine.

The Clerk of the Committee (Mr. William Short): Okay. Thank you.

Ms. Motz, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Leslie Motz: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Mr. Empey?

Mr. Kevin Empey: I'll do an oath.

The Clerk of the Committee (Mr. William Short): Swear an oath as well? Okay.

Mr. Empey, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Kevin Empey: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Dr. Leta Forbes? Ms. Forbes, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Dr. Leta Forbes: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Mr. Tom McHugh. So, Mr. McHugh, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Tom McHugh: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you all for that. Now, as we have been doing with others, we will have 20 minutes for you collectively to make a presentation and then we'll start with questions. We'll start this time with the government side, Ms. Jaczek.

Ms. Helena Jaczek: I start—

The Chair (Mr. Ernie Hardeman): With the questions, when we get there, yes.

Ms. Helena Jaczek: Didn't I start last time?

The Chair (Mr. Ernie Hardeman): No.

Interjection.

Ms. Helena Jaczek: Okay.

The Chair (Mr. Ernie Hardeman): This is the third delegation and we started with the opposition side, so it will be you who gets to start.

With that, again thank you very much and we turn the floor over to you for starting with your presentation.

If I could, just for a moment, each one who speaks, if you would introduce yourself for Hansard to make sure that we get the correct person on the record for having said it. The floor is yours.

Mr. Kevin Empey: Okay. Thank you very much. Good afternoon and thank you for inviting us here to speak with you today. You've invited a number of members of the Lakeridge Health team, so I'll do most of the introductory speaking and introduce everyone.

I'm Kevin Empey, president and CEO of Lakeridge Health. I've been here since 2008. Before that, I was an executive vice-president at University Health Network and I've had senior executive positions at Peel Memorial, which is now part of William Osler, and then St. Michael's Hospital.

Over to my left is Tom McHugh. He's the regional vice-president of cancer services for our whole LHIN, the Central East LHIN, as well as vice-president of clinical services at our place, Lakeridge Health. He came to us last year and was previously the CEO of Tillsonburg District Memorial Hospital, as well as Alexandra Hospital in Ingersoll.

To my immediate left is Dr. Leta Forbes. Leta is the chief and medical director of our oncology program at Lakeridge Health. She is also the quality lead for systemic therapy for the Central East LHIN. She's a medical oncologist, joined Lakeridge in 2004 and became chief in 2011.

To my right is Leslie Motz. Leslie is the senior director of clinical services for Lakeridge Health. She has leadership responsibility for both our pharmacy program and our surgical program. She's a registered nurse with 14 years of hospital leadership experience.

The other two you invited are behind me: Tamara Dus—oh, I'll start at the left. Aaron Lazarus is our senior director of communications. He may be a familiar face to some of you, and he joined our team just over a year ago.

Then beside him is Tamara Dus, who's our admin director, as we call them, of the cancer program at Lakeridge Health and for cancer services in the Central East LHIN. She's a registered nurse who has been with our oncology program for 17 years and has had leadership positions at Lakeridge for the past six years.

I'd like to start by apologizing. We're all here today because hundreds of people and their families, who were already in a vulnerable state, were dealt some incredibly unsettling news. That's difficult for all of us, but the anxiety people are feeling is very real, and I'm truly sorry that any of this happened.

We will talk about how we managed each of our patients shortly.

Health care is a complicated business, and mostly because each patient encounter is unique, let alone that there are many players and, in this case, it's not just about Lakeridge. There were many organizations providing health care whose circumstances were different.

We at Lakeridge Health did not make decisions in isolation. We have been working together with the other affected hospitals as we work through this situation. We've been working with Cancer Care Ontario, the Ministry of Health and Long-Term Care, the Ontario College of Pharmacists, Health Canada, our LHINs and the other hospitals. We've been supporting Dr. Jake Thiessen as he's started his independent review.

I want you to know that this is important to us as individuals. Every one of us is involved in health care and got involved to improve the lives of patients. Our priority is therefore those same patients, and this team has done everything it can to comfort and reassure those directly affected.

While we regret the circumstances, we are pleased to be here with you because this gives us a chance to talk about this situation, how we responded and how we're working to make things better in the future. It allows me,

as the CEO, to publicly state the pride I have in this team and the individuals involved for what they have done. They are all trying to do the right thing. It's an opportunity to outline how our response reflects the culture at Lakeridge Health and the culture of everyone trying to do our absolute best.

So I want to start and tell you a little bit about what Lakeridge Health is, who we are and our culture, because that identity has informed how we've dealt with this situation that we're here to talk about.

Lakeridge Health is one of Ontario's largest community hospitals. Every day we care for thousands of people. We do this in locations that are actually spread over six legal municipalities. First, we have four hospitals in Whitby, Oshawa, Bowmanville, as part of Clarington, and Port Perry, as part of Scugog. Additionally, we have the superb Pinewood Centre for addictions and withdrawal management. Pinewood has multiple locations, not only in Durham region but through Scarborough to Clarington. And then we have six other community clinics.

We are proud to offer high quality in what is one of your largest regional community hospitals. We're a regional centre for strokes, for cancer, for mental health and addictions, for eye care, for kidney care and diabetes. And in Oshawa, we run one of the busiest emergency rooms in Ontario.

We advance science as well. We train over 1,600 students every year: medical students from the University of Toronto and Queen's University; nursing and other professional students coming to us from UOIT, Durham College, Trent University and numerous other colleges. We also run and participate in hundreds of clinical trials, mostly for new drugs and many of those within our cancer program.

Two years ago, we did an extensive consultation both within our hospital and with our communities in order to develop priorities and develop a strategic plan. Our community told us that we were good, but they wanted us to strive to be better. Our strategic plan reflects that and is named Excellence—every moment, every day. It has really focused the team on driving improvements in safety and quality. Those are pretty buzzy words today in health care, so I want to explain a little about what it means for us.

Basically, it means that everyone at Lakeridge Health is responsible to improve. It means identifying where we need to improve and setting really clear, measurable goals so we know that we're making a difference.

One area I'd highlight is a program called antimicrobial stewardship, of all of our different programs. Our team works to ensure the patients are on the right antibiotic for the right length of time and not overusing them, because we know superbugs like *C. difficile* can mutate and become resistant to antibiotics the more they are used.

I'm very proud of the team's efforts. The combination of things like emphasizing handwashing and other infection prevention control activities, in addition to the stewardship program, has resulted in a decrease in *C.*

difficile rates at Lakeridge Health of over 90% in less than two years.

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As with C. difficile, every year we identify where we can improve and develop programs to introduce changes and teach all of our staff the new methods. We're also changing how we communicate with patients and are developing other improvement programs. For example, we developed a new falls strategy to help prevent patient falls, and are spreading that across our hospital. Sick patients need to get up and move. That mobility is key to speeding up healing, but if it's too early, it introduces the risk of slips, trips and falls. Our falls prevention strategy helps us balance their need for independence against that risk. So we're really serious about the safety of our patients and always working to improve quality.

It's not just about safety; it's about instilling a culture that learns and innovates. It means that when something goes wrong, like the issue for which we're here today, we have a no-blame culture. It doesn't mean we're not accountable; we are. We definitely need to fix it. But it means that we want everyone to feel comfortable and confident to raise concerns, investigate and come forward with information and opportunities to learn so we can always improve. And that means we encourage our teams to always come forward with suggestions for improvement. An example: When our occupational health team felt that too many nurses were getting injured lifting heavy IV bags over their heads to attach to a standard hospital IV pole where the IV is fairly high, they looked around. They couldn't find a better solution, so they invented a better option themselves with a private vendor, and now we have the first redesigned IV pole in more than 80 years that hospitals around the world are interested in—from front-line staff. Also, our Whitby hospital is the first hospital that introduced a model of care in which a nurse practitioner coordinates and leads the multidisciplinary team.

Our latest initiative is called patient-driven care, and a major component of that project is focusing on the relationship we have with the people who are coming through our doors every day because at the end of the day, these folks are our neighbours, our families and our friends. They deserve the very best. They expect that their hospital is going to take good care of them, but they also expect that we will be honest with them about anything that might have gone wrong, and that brings me to the current situation around chemotherapy medications.

Our cancer program, the Central East Regional Cancer Program, is unique in Ontario. While the Durham regional cancer centre is located in Oshawa at Lakeridge Health, we are also accountable for the cancer programs across four other hospitals, covering the territory from Scarborough to Cobourg and Peterborough.

That same relentless drive for quality and safety improvements applies to our cancer program. Central East has a Regional Systemic Treatment Program—chemotherapy—that consists of nurses, pharmacists, physicians

and administrators from every hospital in Central East. They work together to develop best practice solutions around chemotherapy administration and safety to ensure we provide consistent, high-quality care at every institution. As a result, in 2012, Cancer Care Ontario ranked us the number one cancer centre in Ontario for performance.

You're going to hear, or may have heard already, about the connection between the Peterborough Regional Health Centre and Lakeridge Health, so I want to take a moment to explain that connection, as I understand Peterborough will be presenting here next week. Peterborough is our first partner, and their program has grown with our support. The cancer program offered at Peterborough Regional is "owned" by Peterborough. They're an independent hospital. But we share clinical resources, including oncologists and pharmacists, between the hospitals, including Dr. Forbes. All oncologists come from Lakeridge Health and are cross-appointed at Peterborough. So we ensure that the quality of services in Peterborough are as great as they are in Oshawa. That's just one of the ways that our two institutions are connected. Peterborough and Lakeridge are also connected in a number of joint clinical services, such as thoracic and vascular surgery.

Lakeridge has many other partnerships with hospitals and other service providers in the LHIN, so partnering is in our DNA. We apply the same philosophy to purchasing. I was personally involved with the Ministry of Finance as they were considering creating Ontario-Buys. The challenge we discussed then was the impact on vendors if buying groups became too big. We need more than one vendor for products in Ontario. I can gladly share anything about that with you today, if you desire.

More specifically, Lakeridge Health has joined different joint purchasing organizations for different types of purchases, and we currently are members of three buying groups: Medbuy, Plexxus and HealthPRO.

Generally, the idea behind all of these buying groups is that groups of hospitals making purchases together will drive economies of scale that we would not otherwise achieve. But lower prices are just one potential benefit. By joining together, we will have tighter purchasing practices and be able to leverage training for new products and equipment that can improve patient safety.

There are different buying groups with different purposes, and I'll tell you about two of them today. I was a co-founder of Plexxus, which is a partnership focused in the GTA only, and Lakeridge Health is one of the founding member hospitals of Plexxus. We use Plexxus for specific product lines: medical-surgical, office products and logistics. When it comes to medications, Lakeridge Health is a member of Medbuy. Medbuy is different in that it's a national organization.

Using chemotherapy drugs as an example, the broader public sector supply chain guidelines require that we go to tender regularly. At regular intervals, Medbuy will go through a process to contract particular medications, depending on the availability of vendors. If we always

stayed with the current vendor, the whole process would be a farce, so tendering is serious business. We can provide more information on the process, but it's important in the context of this situation that you know that once a new vendor is identified, the transition has to be worked out, and each hospital can transition over to that supplier at different times.

You of course know by now that the situations in Windsor and London are somewhat different than for us at Lakeridge Health and the Peterborough Regional Health Centre. We only made the transition to this new supplier in mid-March of this year.

Let's talk about this specific matter. We switched to the new vendor for two premixed chemotherapy drugs on March 12, 2013. Our staff became aware on March 20 of concerns around these two particular products, and our team took immediate action and removed them from our supply—and as I say about our culture, they did not wait for executive approval.

Our pharmacy and cancer teams immediately pulled folks together and began investigating, our patients and how they may have been impacted being the foremost priority of the team. We believed that a number of our patients had been under-dosed with one of their chemotherapy drugs. While we knew we still needed to verify the concerns, we had to determine exactly who would have been impacted. That involved a detailed review of patient charts.

Because we had only been using the new supplier for a matter of days, we were able to quickly identify 37 patients who would have been potentially impacted. While that review was started, we considered that patients at other hospitals could be impacted as well. That's when we began calling other cancer centres to let them know we had concerns.

Those conversations led to a table being established through Cancer Care Ontario and the LHINs just prior to the Easter weekend, in order for us to share what we had learned and coordinate our efforts to inform our patients and our communities. We worked through that weekend to coordinate our efforts to inform everyone, and we began the process to inform our patients on Tuesday, April 2.

Remember that we had just recently transferred over to this supplier, so all 37 patients impacted in our hospital were actually still in active treatment. We identified that some of those patients were coming in for their next treatment on Tuesday, April 2. This created an ethical issue, and we concluded we had an obligation to inform people at the earliest opportunity. They also needed to speak to a physician, preferably the physician they were dealing with, to discuss what impact it could have on their treatment.

Our team spoke directly with patients who came in that day, the 2nd, and one patient who came in the next morning. We telephoned the remaining patients to speak with them directly about this, and by 9 a.m. on April 3 all patients affected had been informed.

All patients were given an opportunity to discuss their situation with a physician as soon as possible. Some

spoke to their physician at the time of disclosure, and others by phone immediately. All patients were offered an appointment with their physician as soon as possible.

We then issued an update to patients generally and the media via a news release that was also placed on our website, but we also knew as the news broke publicly that others who were not directly impacted would be worried nonetheless, so we set up a dedicated phone line for people to call and get more information. We posted notices in our cancer centre letting other patients know about the situation, and reassuring them that they were not impacted, and we sent couriered letters to the 37 impacted patients to follow up and make sure they had all of the information available in writing.

Dr. Forbes can speak to this further, but in a nutshell, patients were told that there were 37 patients impacted. Those patients had gemcitabine treatments between March 12 and March 20 or cyclophosphamide treatments between March 18 and 20. Some 31 of our impacted patients had only one dose with a lower than anticipated concentration, and two had two doses.

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These medications are used in a variety of malignancies, such as lymphoma, breast, lung and bladder cancers. You also might not realize that often these drugs are used to palliate symptoms, and, in our case, 27 of these patients were actually receiving chemotherapy for incurable disease, and 10 were receiving chemo in the curative setting.

You've heard about oncologists suggesting concentration. Oncologists also do not adjust the concentration of these kinds of chemotherapy—I'm sorry—do adjust these kinds of chemotherapy, depending on how a person is reacting to the side effects. So it's not uncommon to reduce the dose of one of these medications to ease side effects, often by as much as 10% or 25%. The difference in those cases is it's a decision that's made between the patient and the doctor. In this case, that was not the case. Again, we deeply regret that this has happened.

We are very sorry for the anxiety it has caused people—those going through treatment and those who called, wondering about their loved ones who maybe had passed years ago, and even those who are not in treatment but now have had their confidence shaken.

To everyone, I would like to say we are all working to identify what gaps existed that allowed this to happen, what we have to do together to close those gaps and what are the lessons we can learn from what has happened and apply those lessons to how we conduct ourselves.

Providing health care is an awesome responsibility that none of us takes lightly. It's all we can do in situations like this to investigate, review, learn and improve. That's what we're doing at Lakeridge Health because we believe we owe that to each other. It's the only way we will get to the point of truly delivering excellence every moment, every day. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. We have one minute left, but I think we'll just use that in the circulation here. Ms. Jacek?

Ms. Helena Jaczek: Thank you for your presentation. I'll just start by echoing some of your sentiment. Certainly I think I can speak on behalf of the whole committee, all of us here, that our concern is with those patients. You have relatively few, obviously, compared to Windsor, who we heard from yesterday, with 290, but of course we're very cognizant of the effect that it no doubt has had on those patients and their families and their concerns around the situation. We're here, obviously, to do what we can to make sure this sort of situation does not occur again.

I'd like to start off by saying we're aware that an individual in the Peterborough hospital took it upon themselves to test the product that was new in the hospital. Can you describe to us exactly what happened? Why this happened? Does it relate to your quality assurance program? Because, clearly, you were the one who discovered this problem.

Mr. Kevin Empey: None of us were actually there to know exactly what happened other than that this—whether you want to add anything thing, Leta—technician identified that the size of the bag, the contents of the bag, looked out of line.

Ms. Helena Jaczek: So as far as you're aware, it was a visual, that somehow there was additional saline or something. Can anyone explain how this happened?

Ms. Leslie Motz: We received the call from the Peterborough hospital by one of their technicians to indicate that they were uncomfortable with the bag. They did not give us details on any further testing beyond that. Lakeridge Health actually took that information and then they started to do an analysis of the bags at the Lakeridge hospital and then closed the loop back with Peterborough to share our findings. I'm unaware of any specific tests that were performed at Peterborough, but they could answer that.

Ms. Helena Jaczek: So what was done at Lakeridge, then?

Ms. Leslie Motz: At Lakeridge Health, we sequestered all of the—both the gemcitabine and the cyclophosphamide right away. We sequestered it, put it in a safe environment in a locked pharmaceutical room.

We initially—before management was even advised of the issue—had three pharmacy techs and a pharmacist who actually took one of each of the bags—one gemcitabine and one cyclophosphamide—withdrew all contents and measured the contents by mls, and that was enough for them to know that there was more in the bag than the 100 c.c.s or 200 that was thought to be in the bag. From that point on, we weighed each of the bags, but we did not interfere with any of the other bags. We kept them secured and sequestered.

Ms. Helena Jaczek: So the date that Lakeridge did the testing was—

Ms. Leslie Motz: On March 20.

Ms. Helena Jaczek: That was all March 20.

Ms. Leslie Motz: Absolutely.

Ms. Helena Jaczek: And so then, communication to whom? Who did you contact first?

Ms. Leslie Motz: The pharmacy staff, who did that testing, as soon as they felt that there was an issue, they called the manager of the pharmacy department.

The day was done, so there was no further chemotherapy being given that day. There was a stop order put on, and she advised them to sequester the medication. At that point, I was notified as well that the medication had been sequestered, and that's when we reviewed our stock to ensure we had enough supply in house to continue to service our patients without any disruption.

Ms. Helena Jaczek: Previously, how had you prepared these products? Before you purchased them through the group buy situation, how had you obtained cyclophosphamide?

Mr. Kevin Empey: Before this contract?

Ms. Helena Jaczek: Yes.

Mr. Kevin Empey: We were purchasing them from Baxter before. We were outsourced before as well, and we switched vendors.

Ms. Helena Jaczek: I see. So that was through the tendering process. Why did you choose to go with this? Was it a cost issue with this particular product?

Mr. Kevin Empey: For any purchasing process, any contract, you have to set up decision criteria. I don't have the actual results myself, but there were decision criteria involving price, quality, ability to deliver. What Medbuy, the buying group, does is—they actually have different committees, so they engage members from the field of all their hospitals. Our former director of pharmacy was involved in this, but none of us sitting here today. They form an advisory group that does the tender evaluation.

Ms. Helena Jaczek: How would they have evaluated quality? Are you aware?

Mr. Kevin Empey: I wasn't a party to it so I don't know what is behind, exactly what specific things they were looking for.

Ms. Helena Jaczek: Okay. Now, in terms of notification beyond your institution, when was the Central East LHIN notified? When was Cancer Care Ontario notified?

Mr. Kevin Empey: I guess I'll pass to you, Tom. We first notified another hospital. It was pharmacy to pharmacy, was it not? Or was it cancer to cancer to London?

Mr. Tom McHugh: We did make a call between pharmacies to London and then—I just have my calendar down here—we had intended to notify the LHIN on Tuesday the 2nd, but in fact, all three LHINs affected were notified on the 31st, which was a Sunday, Easter Sunday.

Ms. Helena Jaczek: On the 31st of March.

Mr. Tom McHugh: That's right.

Ms. Helena Jaczek: And you were aware March 20?

Mr. Tom McHugh: That's right.

Ms. Helena Jaczek: I see. So you sort of looked after your situation yourself very intensively as you've described, and I guess we can say thank God this was discovered so quickly, so as you've described, there were only 37 patients impacted. Okay, well thank you for that.

Perhaps we can just talk a little bit more about what has happened since. We know that Dr. Jake Thiessen has been appointed as an expert reviewer. Have you been

involved? Has Dr. Thiessen contacted you? Can you describe that process?

Mr. Kevin Empey: I guess I should declare that we've had two different contacts. The Ministry of Health has set up a daily phone call with all the parties, and Dr. Thiessen attends those phone calls if he's available. So I'm part of a phone call almost every day, if he's there. That's one contact.

Secondly, he has started travelling to visit the hospitals as his first point of contact. He has kind of followed us in order. He was at Peterborough last Tuesday, Lakeridge last Wednesday, and then he has now visited Windsor and London.

Ms. Helena Jaczek: On this daily phone call, you're talking about the working group?

Mr. Kevin Empey: The working group that the Ministry of Health has set up.

Ms. Helena Jaczek: What kind of discussions are occurring with the working group?

Mr. Kevin Empey: More than anything else, it's just confirming what is happening; for example, the release that came out from Health Canada on Friday and the amendments to the Public Hospitals Act. Catherine Brown informed all of us Friday that those were coming out. We're just kind of getting updates from everyone, and Jake is giving us an overview of not the particular details he's getting in the interviews, but let's say his sense of how the interviews are going and whether everyone's co-operating and whether he needs any more help from the advisory panel.

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Ms. Helena Jaczek: Were any of you aware of what I guess we're calling this "grey area" in terms of oversight between Health Canada's responsibilities around manufacturing of pharmaceuticals and the College of Pharmacists' oversight of pharmacists in pharmacies?

Mr. Kevin Empey: No, we were not. This is an unfortunate learning experience for all of us.

Ms. Helena Jaczek: I see. Okay, now that you've heard about the actions of Health Canada and the proposed regulation, do you feel that this is something that will assist in terms of quality assurance in the future? Can you express an opinion?

Mr. Kevin Empey: Yes. I kind of equate it to let's call it the other devices and tools that we use. So if we buy bandages or a hip from a supplier, we know that they're certified by Health Canada. We buy—we obtain blood products; we don't buy them. We obtain blood products so we know that the blood products have been certified. Drugs themselves get a DIN number, and the manufacturers are certified by Health Canada. So it would be great for all of us to have a simple regulation that kind of expands to this group of products as well.

Ms. Helena Jaczek: Maybe I'll just turn to Dr. Forbes and maybe talk a little bit more about the impact on your particular patients—and Mr. Empey, to give us an overview. Could you just explain to us a little bit more, from your professional opinion, about the impact on these 37 patients?

Dr. Leta Forbes: The drugs that were affected were one drug within a multi-drug regimen and, in many cases, were actually not the most active agent of the multi-drug regimen. This was one dose for 31 of our patients and two doses for six of our patients. So in the big picture, this is one small under-dosing of one drug of multiple cycles of multiple agents. So the actual clinical impact, we think, is very minimal.

Ms. Helena Jaczek: Well, that's very good to hear. So how are you preparing these compounds currently, since March 20? How are you getting your supply?

Mr. Kevin Empey: We stopped buying them from Marchese, and our pharmacy has taken the work in-house.

Ms. Helena Jaczek: I see.

Mr. Kevin Empey: So our pharmacy is doing the compounding and the preparing for these chemotherapy drugs.

Ms. Helena Jaczek: Mr. Empey, when you were giving us your overview, you mentioned your relationship to one of these group-purchasing organizations, Plexxus. You were a co-founder. Are you in any way connected to Plexxus in your current position?

Mr. Kevin Empey: Yes. Lakeridge still remains a member of Plexxus, so we do our contracting through them, and this last fall I joined the board of Plexxus.

Ms. Helena Jaczek: I see.

Mr. Kevin Empey: So I'm a board member.

Ms. Helena Jaczek: Can you just detail for us perhaps—you must be a believer in group purchasing. Could you just give us some insight into the advantages of a process like this that you were engaged in?

Mr. Kevin Empey: Sure. I think there are a number. One of them is definitely purchase price. Many of us believe that if you can increase the purchase quantity—so a whole bunch of hospitals going out together—you will get a better price, and Plexxus has generated significant purchase-price savings over its eight or so years.

Secondly, something I mentioned in the speech is what I call the standardization of the process of hospitals going out together. You now have one process with one set of criteria versus, say, seven or eight hospitals going out themselves with individual criteria and doing very different evaluations on the exact same thing.

Then, anytime you make a change, like take Baxter to Marchese, you have to have an implementation period, and if it's something new like, say, a new IV pump, you have to go through an awful lot of training with your staff. So getting that standardized approach to the training and getting support from the vendor is really critical to make sure that we implement it properly.

Sometimes we will make a contract choice where the price actually goes up, but we're making the change for an improvement in quality or safety.

Ms. Helena Jaczek: Can we assume that when you started your original contract with Baxter, your very excellent pharmacy technicians and pharmacists took a very cautious approach, the way they did with this particular product? Is this the norm in your institution, that

there is a very careful analysis of the new product received?

Mr. Kevin Empey: Unfortunately, none of us would have been involved in this when we started buying from Baxter, to be able to answer what we would have gone through, but yes, you have to do that. You have to do an evaluation when you first receive it to make sure that you're buying what you said you were buying.

Ms. Helena Jaczek: How much time do I have left, Chair?

The Chair (Mr. Ernie Hardeman): You have about a minute and a half.

Ms. Helena Jaczek: Okay. I'll save my minute and a half. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. The opposition, Mr. O'Toole.

Mr. John O'Toole: Thank you very much, Kevin and the Lakeridge experts. I just wanted to be here out of respect for the work you do. I'm very impressed with the report you have given to the committee, and I recognize the empathy you have for your patients or clients, however you describe them. I also want to recognize as well that Christine Elliott, our health critic, couldn't be here today. She reminded me to perhaps attend out of respect for that discussion.

I would also say that I was made aware and had access to a full briefing. As you know, I think we had a full breakout in the number of patients, the 37. To be helpful in terms of not making a bad situation worse—people's knowledge and the reaction, I think, was professional and respectful. I say that without being a full member of this committee but I am very interested in health care generally. My colleagues are here to question or at least bring to light some clarification in your report.

Thank you very much, Kevin. That's primarily all I have to say. Thank you again for coming.

The Chair (Mr. Ernie Hardeman): Thank you very much. Mr. Yurek?

Mr. Jeff Yurek: Thank you very much for coming today. I appreciate the work you do in your community. I'd also like to commend the pharmacy technicians for their professionalism and detail to their job in finding the error. I think that was great. That shows the level of competence in our health care professionals throughout the province, that that was picked up by them. I appreciate that.

My first question of all is with regard to procurement policy. Outside of the broader public sector directive from the Ministry of Finance, does the Ministry of Health have any procurement policy put together in regard to obtaining compounded medication outside of the mainstream drug manufacturers?

Mr. Kevin Empey: Do you mean a policy applying to hospitals?

Mr. Jeff Yurek: Yes.

Mr. Kevin Empey: I don't know that there's a discrete policy other than all of our responsibilities under the Public Hospitals Act to follow rules and regulations, generally.

Ms. Leslie Motz: And the College of Pharmacists has numerous standards around the preparation of compounded medication, and many best practices and training received as well from the college.

Mr. Jeff Yurek: I'm a member of the college.

Ms. Leslie Motz: Sorry; I was unaware of that.

Mr. Jeff Yurek: Just to give you the information.

The Chair (Mr. Ernie Hardeman): He's the plant.

Mr. Jeff Yurek: I'm the plant.

You noted earlier that with blood products, you have to make sure they come from a certified provider. Drug manufacturers, of course, are certified through Health Canada. You buy hips from certified providers. But there was no direction that compounded medications have to come from an accredited, certified provider. Is that what was maybe missing from the Ministry of Health?

Mr. Kevin Empey: Well, this was honestly a gap in our knowledge. We didn't know there was a distinction. Medbuy themselves, all the people involved in this, we didn't catch the distinction between the legal structure of different companies and whether there was any difference from the Marchese pharmacy—that we should be looking for anything different. All the vendors are asked in every tender if they are selling us a legally licensed product, so we can only assume that conversation happened and no one on our side caught any impact of a structure or regulatory grey area.

Mr. Jeff Yurek: So to your knowledge, does Medbuy have a pre-qualification for manufacturers that want to sell product to Medbuy, to the hospitals? Is there a pre-qualification to ensure that they're accredited?

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Mr. Kevin Empey: I don't know. I can't comment on whether or not they have a pre-qualification. I know that all of us are very interested in making sure that they're valid products, so Medbuy has those questions as part of every tender process.

Mr. Jeff Yurek: With regard to March 20, when you found out about the possible error, was there any policy coming from the LHINs or the Ministry of Health to inform them of a potential error in the system so that they could spread the knowledge to all hospitals?

Mr. Kevin Empey: I wouldn't say there was a policy as much as a practice—but also, we're cautious. We do not start spreading until we have a pretty good idea that we really do have a problem. This first detection, as Leslie Motz said—we wouldn't start talking to other institutions until the pharmacy has done more review and we're really convinced we have a problem. So we don't even raise the alarm to the LHIN until we're convinced.

Mr. Jeff Yurek: It's up to the individual hospital to contact other hospitals? There's no overriding central part of the system that would do an alert across the province?

Mr. Kevin Empey: There's no central system. I'd say that there are channels. Cancer Care Ontario only has responsibility for the cancer centres. This happens to be cancer, but if it wasn't cancer, our two channels would be to the LHIN and to the Ontario Hospital Association. The

Ontario Hospital Association has been actively involved in this, in sending out information to the rest of the 154 hospitals. That tends to be our process.

Mr. Jeff Yurek: My understanding of the drug system, as you know, is that when there's a recall per se of a drug, Health Canada sends out an alert to pharmacies across the province, and then it's followed by mountains of paperwork from both Health Canada and the supplier. But there's nothing in place that would occur for a hospital if they found an error with a product they have procured outside of manufacturers—

Mr. Kevin Empey: I honestly don't know whether we would be subject to lawsuits if we did what you just said. We have to be careful of whether we're defaming a vendor publicly, so we tend to do it with phone calls. In this case, there aren't just cancer centres, but there are 71 hospitals that provide chemotherapy. So Cancer Care Ontario orchestrated a phone call to every one of those hospitals.

Mr. Jeff Yurek: The point of my question is not to defame any vendor. If you look at our water system out there, if there's a problem, the medical officer of health of that area is contacted. At least there's somebody who has dedicated responsibility—probably a former Chief Medical Officer of Health—that there's a problem. But I don't see any linkage from the Ministry of Health that would have that system put in place.

Mr. Kevin Empey: Right. I'm not aware of any regulation or any demand that says, "You report this way, using this purpose."

Mr. Jeff Yurek: From what I'm listening to and from the other days of testimony—not testimony, because you're not on trial, but I think you understand—there are no guidelines from the Ministry of Health or LHINs for procurement of compounded medication in the system. Basically, the broader public sector definition is about all you get from the Ministry of Finance.

Mr. Kevin Empey: Right. The ministry does not get involved in our specific procurement process or our specific procurement decisions. Some hospitals buy in buying groups, like we do; some hospitals are purchasing on their own.

Mr. Jeff Yurek: Nor would I want them involved in the day-to-day operation. But I'm looking at some standards to ensure quality or quality control—

Mr. Kevin Empey: Well, in effect, the public sector supply chain guidelines created those standards. This is the expectation of, when you go to tender, what you have to involve in the evaluation process. But they don't get to the point of stating, "These are your decision criteria," because, honestly, our decision criteria are very different depending on what the type of drug is.

We were having a conversation earlier that depending on what the product is, whether you involve the clinicians or whether the clinicians are involved in the hospital—in the case of drugs, pharmacy and therapeutic—process of getting a drug onto what we call the formulary. So we have different processes depending on what

the product is. If it was a rigid one-shop, we would probably all have problems as institutions.

Mr. Jeff Yurek: My concern is the fact that the broader public sector supply kind of encompasses anything from laundry service to whatever product, and this procurement of medication outside the hospital is rather new, especially with compounded medication.

Last Friday, the ministry announced that they're changing the regulation. They can only purchase from accredited, licensed or otherwise approved suppliers. Common sense, in my mind, dictates that it should have been the standard—

Mr. Kevin Empey: That's a normal question anyway.

Mr. Jeff Yurek: —it would have been the standard in that process.

My concern with the system was that was lacking when this new type of procurement occurred; that the Ministry of Health, which has a deputy minister of the health system accountability and performance division, has a whole section of people, and this was missed when a new type of procurement—to me, that relates to the dawn of the Internet and allowing hospitals to switch to the Internet, but don't put in any new policies. Don't rethink what's going on; the old rules will suffice.

I guess that's more a statement than a question, but if you have any thoughts on that I would be appreciative of any response.

Mr. Kevin Empey: I don't know that I could add anything to your statement.

Mr. Jeff Yurek: We'll hold our minutes till the next round.

The Chair (Mr. Ernie Hardeman): Okay, very good. Ms. Gélinas.

M^{me} France Gélinas: It's a pleasure to see you. Thank you for coming to Queen's Park. I have no doubt that you've probably had a couple of tough discussion days, and I thank you for all the work that you've done to help people manage that news and, I would say, turn the page on something that should have never happened, but did.

I was quite impressed with—I'll call it your mission statement—your excellence every moment, every day. This is something to be proud of. As you started to explain, it means that when something goes wrong like the issue, there is a no-blame culture; that you are still accountable and that everyone feels comfortable and confident to raise concerns—I'm reading from your notes. And it worked; it worked. You had a pharmacy technician who noticed something and felt empowered enough to move this issue forward. It got tested by your pharmacy, and basically you exposed what we now know as the diluted chemotherapy.

I would be interested in knowing who this technician is, if you could share that with us, as well as the names of the people who did the initial testing. In answers to my colleague, you made it clear that you didn't call it a problem until you had paid due diligence, that there was a team within your pharmacy that made sure that we had

a problem. It was not just a hunch. If you could table that with the Clerk—or do you know it by heart?

Mr. Kevin Empey: I do not know the technician's name.

M^{me} France Gélinas: Okay.

Mr. Kevin Empey: I did not ask. Everyone is trying to approach this technician, but you will have Peterborough visiting you next week.

M^{me} France Gélinas: Okay. The Clerk will follow up with you, if you could table that information with the Clerk.

Another little piece that I was interested in also is that you note that there are decision criteria that were used to decide which supplier was going to—but you didn't know what those criteria were off the top of your head, which I understand. This is something else that I would like you to table with the Clerk. Will is our Clerk. He will also follow up with you so that we have a better understanding as to how that particular decision was made.

Going into some of the questions, I'll continue with you, Mr. Empey. It has to do with some of the statements you've already made. You didn't know about the grey area. I don't blame you for this; it's not your job to know that kind of stuff. But just to be on the record, had you known that this was an unregulated agency that was procuring you the drugs—if that had been a known fact, do you figure you would have still made that purchase? Any of you can answer.

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Mr. Kevin Empey: I guess I could just say, morally, that we really work hard to conform to regulations. We really work hard to make sure our vendors are giving us safe, evaluated product. I think what it would come down to is this current question: Do we have the capability of doing something in-house or do we have to go out? If we have to go out, are they the only choice? If all other criteria are equal, we would go with a certified vendor. If we knew this, we probably wouldn't have switched vendors—if we knew that there would be this uncertainty about their status. But if they were the only vendor out there, then our next step would be to do an evaluation of whether we could be sure that they had a quality manufacturing process that we could be happy with.

M^{me} France Gélinas: Makes sense. Thank you.

I'd like to ask you a few questions, Dr. Forbes. I take it that you're a practising oncologist?

Dr. Leta Forbes: Yes.

M^{me} France Gélinas: Do you solely practice in hospitals or do you do community? Do you have a practice outside of the hospital as well?

Dr. Leta Forbes: I have in-hospital practices in Oshawa, Peterborough and Cobourg.

M^{me} France Gélinas: I take it you rely not only on hospital services but also the lab reports that come from outside of the hospital, not just within. Am I right?

Dr. Leta Forbes: Yes, that's a fair assumption.

M^{me} France Gélinas: I'm also making a pretty educated guess that in order to do your work, in order to

come to the decision as to, this is the treatment plan for this particular patient, you rely on many, many sources of information, be it the lab, the X-ray, the MRI, the CAT scan etc., and you trust those results to be true. Am I right?

Dr. Leta Forbes: Yes. I think that's a fair assessment.

Mr. Kevin Empey: But if I could answer that: not always. We, a big hospital, have a big lab and we have a big radiology service. Sometimes radiology might determine they're not necessarily happy that that place—wherever—has the same quality of diagnostics that we do, so then we will ask to do the test over ourselves. So if we have any reason to believe we're not happy that their equipment is as current as ours or up to the same standard, we might decide for our clinicians to do something new. Otherwise, we will rely on everyone being regulated and that the clinicians can rely on that test.

M^{me} France Gélinas: Okay. How would you come to the realization of that, that you would like a test redone because you're questioning the quality or you're questioning an outside supplier? How are those decisions made?

Mr. Kevin Empey: Not usually based on facts; maybe based on clinicians' past experience with not being happy with a diagnosis or a test result, and so deciding to do it again ourselves just for caution.

M^{me} France Gélinas: Back to Dr. Forbes: When you practise, do you feel that the information that you get—that it is your job to check if those suppliers are supplying you with right and accurate—that they're accredited and that they are regulated? I'll let you answer that.

Dr. Leta Forbes: When you're practising medicine, every decision you make has a lot of different contributing factors, so you look at the patient. You look at how the patient is; you look at their physical status. You correlate that with what you see on their labs. You correlate that with what you see in their radiology. You never make a decision in isolation. Anytime you have something that's not consistent, then you may end up repeating it or doing a different test. It's not within the scope of a physician to ensure that their supplier is accredited. It is within the scope of a physician to use our clinical judgement to be able to tell if a test is consistent with the clinical picture.

M^{me} France Gélinas: Makes sense. Thank you.

Did you have a question? Go ahead. Don't tell me; tell them.

Ms. Cindy Forster: Ms. Gélinas asked for the information to be tabled with respect to the criteria used with the supplier; she asked you to table that with the Clerk.

I think her question was around the chemotherapy drugs, right? But could you also table the criteria for any drugs that you're actually outsourcing? If you have other drugs within your system that you're having mixed elsewhere outside of the hospital, could you table the criteria that you use to determine that and evaluate it?

Mr. Kevin Empey: So, do we have any other contract other than Baxter now?

Ms. Leslie Motz: No.

Mr. Kevin Empey: We only have one contract for outsourcing compounded medication. It would be all under this contract that we're talking about. There are different drugs, but all under the one contract.

Ms. Cindy Forster: All under the one contract? Thanks.

M^{me} France Gélinas: I'll start with you. How much of a surprise was it to you that there was this grey area and that the part of Marchese that had been supplying—although for a short period of time—these chemotherapy IV drugs, was not regulated?

Ms. Leslie Motz: It was a great surprise to me. I would have expected for the label to reflect the content.

M^{me} France Gélinas: You would? And what do you base this on? Your experience?

Ms. Leslie Motz: Yes, it's my experience, the experience of the pharmacists and pharmacy techs. There is a general practice that there's a significant amount of trust put in the label and the accuracy of labels. Since there is really no internal way of checking that, beyond an investigative sort of role, there is a lot of trust put in the label.

M^{me} France Gélinas: And you are comfortable with that trust because years of experience in the system had shown you that they are trustworthy? I shouldn't have said that. You're comfortable with that trust because—

Ms. Leslie Motz: You said it beautifully. Years of experience, and no quality concerns identified—certainly in my experience—in the past.

Mr. Kevin Empey: If I could add?

M^{me} France Gélinas: Sure.

Mr. Kevin Empey: In our industry, the majority of the vendors are very big companies. So, right there, they're an American international company, regulated in many forums around the world, so you also have a degree of comfort in who you're dealing with just because of the size of the institutions, like a Baxter.

M^{me} France Gélinas: I think you went exactly the way I thought you would go; that is, because of the layers of regulation within the system, everybody within health care feels secure—and trusts—that what they're getting, whether it be a result, whether it be a drug, whether it be an artificial hip or knee, has gone through so many layers of regulations that you can trust that what you got is what's written on the package or what you can see. It came as a huge surprise; it came as a surprise to all of us.

Then come the tough questions for you, and I'll see who wants to be the tough person answering that.

We knew, since 1997, that there was this grey area with no regulation. Do you have anything to say about a 15-year gap in action? Why did it take 15 years to act and close that grey area? I can feel that the CEO is ready to be the brave one on that one.

Mr. Kevin Empey: But my answer won't satisfy you, because the answer is I didn't know that. We heard reference to that in one of the earlier hearings, earlier meetings. We talked amongst ourselves, and none of us had heard that this issue had been raised before. We, as

buyers, knowing that, should have been ultra-cautious with the vendors.

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M^{me} France Gélinas: Had you known.

Mr. Kevin Empey: Had we known, we probably would have changed how we'd approached the tender.

M^{me} France Gélinas: Okay. I'll save my time.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Chair. Mr. Empey, you've obviously explained that hospitals are independent entities and that they have their own board of directors, and therefore purchasing decisions are made, essentially, locally. However, yesterday, when Windsor Regional was here, of course, they reminded us of the Excellent Care for All Act and, pursuant to that, the need for a quality improvement plan. Within that quality improvement plan, they certainly have a very detailed medication-error type of reporting and analysis on an ongoing basis.

Could you just tell us how that works at Lakeridge, in terms of medication errors and the process you follow?

Mr. Kevin Empey: Well, we have a general process for errors, and a system we call the better system, where people record incidents of any kind. Medication would fall under that, and then we have specific people assigned to review the item noted and then draw it to the attention of whether it's the director of pharmacy or others. Then, they collectively decide whether that warrants a review or not. So we have a very formal process to try and make sure that people are actually identifying the errors, or even what we call near misses, because we can learn as much from those as we can—so we don't have anything different for pharmaceuticals. It falls under our overall errors-and-issues protocol.

Ms. Helena Jaczek: And this is reported through the quality improvement plan, I presume?

Mr. Kevin Empey: Not necessarily. The quality improvement plan allows a fair amount of leeway, meaning the objective isn't for us to just focus on five things. The objective is for us to identify the things that are most important for Lakeridge to work on and to improve. There are some mandatory items. We put what's called medication reconciliation, matching the drugs that a patient comes with versus what the doctors might prescribe in the hospital, and we put the falls program that I referred to—things where we knew we needed to improve. We identified those in our quality improvement plan.

Ms. Helena Jaczek: And the quality improvement plan goes to the Central East LHIN and gets approved?

Mr. Kevin Empey: No. Actually, our formal reporting for quality improvement plans is to Health Quality Ontario. We give the LHINs a courtesy copy, but the LHINs don't approve our quality improvement plan. Our board approves it, and then it goes to HQO for review.

Ms. Helena Jaczek: Okay. Thanks.

The Chair (Mr. Ernie Hardeman): Ms. Jaczek, that's the end of your time. We'll now go to Ms. McKenna.

Mrs. Jane McKenna: I just want to jump in and say that we're very grateful that you're here today, giving us the information that you're giving us. My first question is: Do the 37 people have a direct line to the oncologist?

Dr. Leta Forbes: The 37 patients who were contacted were all provided contact information, so a direct line to call in with concerns. They were all spoken to by phone by our staff personally. They were given handouts with a phone number, and yes, they all have a line directly to the oncologist that they normally see.

Mrs. Jane McKenna: Okay. Thank you very much. My next question is: Does the hospital have a contract with Marchese directly or with the broker, Medbuy?

Mr. Kevin Empey: This incident has raised this other curiosity that I must admit I wasn't aware of. We signed a contract with Medbuy and participate in their negotiations of contracts. Medbuy actually has the contract with the supplier.

Mrs. Jane McKenna: So who actually develops the contract? Is it Medbuy that puts all the information into that contract, is it you, or who is that?

Mr. Kevin Empey: It's Medbuy, as a legal entity, that takes the responsibility, but they involve people from the field. They have hospitals like us, customers like us, across the country, so they involve those in the determination of the criteria and the final contract, but Medbuy writes and signs the final contract.

Mrs. Jane McKenna: So they're responsible for that contract and everything that's in it.

Mr. Kevin Empey: Yes, so that's why it was more important for us to contact Medbuy than it was the LHIN in evaluating the contract.

Mrs. Jane McKenna: Right; okay. My next question is: Marchese maintains its drugs were not defective, suggesting the problem was how the drugs were administered at hospital, not how they were prepared. How easy is it to make this kind of compounding error if you're a qualified pharmacist?

Mr. Kevin Empey: I'm an accountant, so one thing that the team had to educate me on was that most of us do not realize that an IV bag says it has 100 c.c.s in it; it almost never has 100 c.c.s in it. Every IV bag has a randomness to it. The clinicians can correct me for saying this wrong, but that doesn't matter that much when you're injecting a medication into the IV bag and then you have an IV drip and you're going to dispense the whole bag into one of us, because you know you're getting the whole medication. The difference with chemotherapy drugs is, it's that ratio of medicine to IV that is critically important, so we need to know how many c.c.s are in that IV bag. Kind of, for the other IV bags, don't worry about it. So that's the significant difference of this product. We need to know how many c.c.s are in that bag.

The Chair (Mr. Ernie Hardeman): Mr. Yurek?

Mr. Jeff Yurek: I've just got a couple more questions, thanks.

With regard to the labelling of the bag coming in from Marchese, we heard yesterday they labelled it four grams

and 250 mls. Did any pharmacy staff ever have concerns with the way the bag was labelled, perchance? My concern is, I don't know why—it's easy to do math with a concentration on the bag, let alone just four grams and 250 mls.

Mr. Kevin Empey: Honestly, it was apparently one of the reasons Marchese was picked, according to one of the other hospitals. It was that their bag labelling was much clearer and much more precise than the other vendor—ironically.

Mr. Jeff Yurek: Okay.

Mr. Kevin Empey: So the labelling was great; it was just this issue about the vagary of the amount of IV saline that was in it.

Mr. Jeff Yurek: We also heard yesterday one of the reasons this drug is procured is just because of the difficulty to get the powder into the solution, and the time. I imagine it would be more of a time problem. Has that been a problem—switching back—to the hospital, with regard to staff time and such?

Ms. Leslie Motz: Has it added workload and challenged the capacity? It has. Are we comfortable and confident that we are doing it and meeting all best-practice standards? We are.

Mr. Jeff Yurek: And your staff are all trained up to date with chemotherapy—that mixture?

Ms. Leslie Motz: They absolutely are.

Mr. Jeff Yurek: Okay. That's good.

The Chair (Mr. Ernie Hardeman): Thank you very much. France?

M^{me} France Gélinas: So I can use my time wisely, how many minutes have I got left?

The Chair (Mr. Ernie Hardeman): Four.

M^{me} France Gélinas: Four. Wow.

The Chair (Mr. Ernie Hardeman): Starting now.

M^{me} France Gélinas: We'll have to speak really fast. I may have to switch to French; you just don't know.

I take it that you have a relationship with Medbuy, since they do some of the purchasing for you. Who is your primary contact?

Mr. Kevin Empey: The primary contact would be pharmacy to pharmacy. We have a second primary contact, which is that our vice-president of finance is on the board of Medbuy.

M^{me} France Gélinas: No, I mean—okay, so who is that person at Medbuy who you deal with?

Ms. Leslie Motz: On a day-to-day basis? Is that what you're asking?

M^{me} France Gélinas: Yes.

Ms. Leslie Motz: There's a director at Medbuy who is our direct first contact.

M^{me} France Gélinas: And his name is?

Ms. Leslie Motz: Her name—

M^{me} France Gélinas: Her name.

Ms. Leslie Motz: —is Ann Kelterborn.

M^{me} France Gélinas: Could you say the last name again?

Ms. Leslie Motz: Sure. It's Kelterborn.

M^{me} France Gélinas: For this particular contract where you decided to procure the chemotherapy through Medbuy, who was the person you dealt with at Medbuy?

Ms. Leslie Motz: I wasn't part of the contract, so, I'm sorry, I can't answer that.

Mr. Kevin Empey: It was our former director who was on that contract team, so we would have to go back to learn who was the main contact that she was dealing with. For us, it's an operational issue, the day-to-day contact with the day-to-day players.

M^{me} France Gélinas: Okay. If you could table that with the Clerk, please, who it was that your hospital negotiated with at Medbuy regarding that particular purchase—the supplying of the chemo drugs.

So the minister on Friday put the draft regulation in place that basically says, “You will have to purchase from accredited suppliers.” How will you do that? You didn't know that they were not accredited. Had you known, you wouldn't have. So how are you going to fulfill that?

Mr. Kevin Empey: I don't know the answer to that question other than do what we did during the tender, which is to ask the question, “Are you accredited?” So then we're still reliant on them. We larger hospitals may have more opportunity with bigger purchasing functions to do more investigation of the company, but it would be a concern for small—smaller hospitals don't have those resources to be investigating all the vendors.

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M^{me} France Gélinas: But small hospitals also purchase chemotherapy and also provide cancer treatment.

Mr. Kevin Empey: My answer was thinking broader than chemotherapy—products in general.

M^{me} France Gélinas: Okay. So, basically, you will still be reliant on whatever they tell you.

Mr. Kevin Empey: Right, and they are accredited by the College of Pharmacists. We didn't understand that distinction, so a lot of hospitals, not knowing this, would have just accepted that.

M^{me} France Gélinas: Absolutely. So would I, and so would everybody else.

It feels like a transfer of responsibility. The Ministry of Health is the overseer. They are the steward of the health care system. They don't deliver care; good people like you do this. They make sure that the system has oversight, is regulated, is basically accountable. Would you see it as reasonable to ask the ministry to do this accountability to make sure that the suppliers out there are regulated?

Mr. Kevin Empey: Let's say it would be simpler for the field if we didn't all have to come up with our own answer to that question. Whether it's the Ministry of Health or Health Canada, it would be really simple to know that there's one body we're relying on.

M^{me} France Gélinas: Would you say it would make sense to have it with this one body, either Health Canada or the Ministry of Health?

Mr. Kevin Empey: I'm just saying it would make it simpler for all of us in the field.

M^{me} France Gélinas: Okay. I get you.

The Chair (Mr. Ernie Hardeman): This being your last question.

M^{me} France Gélinas: Oh, no. How did that happen?
Interjection.

M^{me} France Gélinas: Huh?

Mr. Jeff Yurek: We'll ask them for you.

M^{me} France Gélinas: You'll ask them for me?
Did you want the last question?

Ms. Cindy Forster: No, go ahead. You're on a roll.

M^{me} France Gélinas: I guess the last question will be to you, Dr. Forbes. We're all really sorry for what has happened. You were very reassuring today when you told us that for the 37 people who were affected in your hospital, it was one dose of a mix, sometimes two doses of a mix. You were pretty explicit in saying that for those people, you feel pretty confident that the rest of the treatment will do whatever it was aiming to do.

Would you feel just as confident to say that the trust factor was as easy to convince than the actual aim of the treatment?

Dr. Leta Forbes: I think you're going to have to be a little bit more clear. Who are you referring to?

M^{me} France Gélinas: Mainly patients, families, people who deal with your hospital, people who deal with the cancer program that you are a part of. The issue of trust is integral in providing care. Once the trust is broken, it's a lot tougher to provide care. I'm trying to see how much of an impact you figure this has had, for good or for bad.

Dr. Leta Forbes: Our patients have a great deal of faith in us as their clinicians. We have excellent relationships with them. They trust us completely. There is a concern amongst patients who weren't affected and patients who were affected that other drugs that they're receiving are not what we say they are, so we are doing everything we can to reassure them that we have taken all the steps we need to do to give them what we say we're giving them. But there has been trust affected in the population. There's no doubt about it.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. McKenna.

Mrs. Jane McKenna: First off, I want to say that there are 362,000 pieces of regulation. You being in the hospital would know that, at times, it's overwhelming to have all of these regulations to even get to the front line of the patients themselves. Considering that this was a grey area since 1997, my first red flag tells me that it's time that we actually go and look at each piece of these regulations to see what works and what doesn't work—because you can't continue adding on red tape and regulation after regulation, because here's an example here of what happens: One hand thinks the other hand is doing it.

I have a question. The more players involved, the greater the opportunity for mistakes. Would you say that the need for regulation and oversight is even greater when you have so many people with their hands in one situation?

Mr. Kevin Empey: The one situation specifically being chemo drugs, you mean, or drugs in the system of health care?

Mrs. Jane McKenna: The whole thing. Either or.

Mr. Kevin Empey: Well, the system of health care has the problem in that it's even greater. You have long-term-care homes, retirement homes, EMS, CCACs, home care and hospitals all procuring drugs on their own and all slightly subject to different regulatory frameworks—because we have the overriding Public Hospitals Act, and not all of the rest of those have that, like the Ambulance Act for EMS.

Any group of people, any institution in this sector has to be careful. We deal with EMS; we deal with the CCACs. We have to talk to them to make sure of whose regulations take precedence. I doubt you'd get one overall regulation that deals with the whole health care system, though. It's too complicated, which is why there are so many different acts.

Mrs. Jane McKenna: I'm not disputing the fact that you can't have one, but what I am saying—I'm just saying we need to look at what's there. This is a tragedy that we need to be able to look at to see how we could miss the gaps in the overlap.

I guess my next point is, if it was so noticeable to the technician—the other hospitals would have had the bag from before and then the new bag. They would have seen exactly what the technician saw at your hospital if it was so noticeable. My question is, how come nobody else noticed it?

Mr. Kevin Empey: We can't really answer that, but I can just bring you back to the point of why I talked about the variability in IV bags. People get used to the fact that every IV bag has a different quantity in it.

Mrs. Jane McKenna: Right.

Ms. Leslie Motz: I could add a little bit of detail. When we switched vendors, the previous vendor had been preparing in an empty bag, if you will, so the look and the feel and everything were different about it. With the exception of this one astute person who had a guttural reaction to something, I'm not sure anyone else would have been able to recognize 20 c.c.s in a bag of 200. That would not be that noticeable compared to the previous provider, which was using an empty bag. So they were adapting to a new system as well.

Mrs. Jane McKenna: It's just amazing to me that this person did. If it's 20 c.c.s and it's minimalistic, it's just amazing to me that this person did.

The Chair (Mr. Ernie Hardeman): Mr. Yurek, do you have another question?

Mr. Jeff Yurek: Sorry, just with regard to the labelling of the product, you made the comment that

Marchese actually had better labeling. What did Baxter—what was on the labeling of their bag?

Ms. Leslie Motz: Both labels, from my recall, were ISMP. There was no concern around meeting the qualifications of the label. The difference is that the Baxter label provided the concentration whereas the Marchese label did not provide that concentration.

Mr. Jeff Yurek: That would tell me that the Baxter label was a little more informative for a health care professional.

Ms. Leslie Motz: I'm sorry?

Mr. Jeff Yurek: That tells me the Baxter bag would actually be a little more informative for a health care professional using that bag in order to create the accurate dose. It just makes the math a little easier.

Ms. Leslie Motz: The other difference was the bar-coding. Marchese offered bar-coding on their labels. The previous label did not offer bar-coding.

Mr. Kevin Empey: That's a detail I wanted to add. Our health system is laggard in the use of bar codes. More and more, we hospitals, our buying groups, are demanding that as one of the criteria in making a selection. If you give too much weight to it, you're not necessarily balancing the other because we need to move to the electronic age with bar-coding.

Mr. Jeff Yurek: So what would the bar code information inform the pharmacy technician of?

Mr. Kevin Empey: I can't read a bar code or anything off of it, but a bar code allows you inventory control and product control using electronic inventory systems. It's much faster and much more efficient in terms of inventory management—

Mr. Jeff Yurek: And bar codes for the inventory management, not for transfer of what's on the label or anything.

Mr. Kevin Empey: Not for transfer of the medication information, no.

Mr. Jeff Yurek: Okay. So that's separate.

The Chair (Mr. Ernie Hardeman): Thank you very much, Mr. Yurek. That does conclude the time. The inquisition is over.

Thank you very much for being here to help us out with some of these issues. You've been very informative, and we very much appreciate you taking time away from what you could be doing on this nice spring afternoon. Thank you very much for being here.

That concludes the committee meeting this afternoon. The next meeting—we will reconvene here on April 29—that's next Monday—at 2 o'clock. Thank you all for being here.

The committee adjourned at 1720.

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Journal des débats (Hansard)

Lundi 29 avril 2013

Standing Committee on Social Policy

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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 29 April 2013

Lundi 29 avril 2013

*The committee met at 1414 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIES

The Chair (Mr. Ernie Hardeman): Seeing that petitions have just ended, we'll call this meeting of the Standing Committee on Social Policy to order. We are meeting for a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

LONDON HEALTH SCIENCES CENTRE

The Chair (Mr. Ernie Hardeman): Our first delegation this afternoon is London Health Sciences Centre, here to help us understand what went on.

With that, first of all, we'll ask the Clerk to do the swearing in, as we will be doing it all under sworn testimony.

The Clerk of the Committee (Mr. William Short): I'll start left—my left—to right. So, Mr. O'Hara, correct?

Mr. Toby O'Hara: Correct.

The Clerk of the Committee (Mr. William Short): Did you want to swear an oath or be affirmed?

Mr. Toby O'Hara: I'll swear.

The Clerk of the Committee (Mr. William Short): The Bible is there.

Mr. O'Hara, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Toby O'Hara: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Mr. Johnson?

Mr. Neil Johnson: Yes?

The Clerk of the Committee (Mr. William Short): Same thing?

Mr. Neil Johnson: Yes.

The Clerk of the Committee (Mr. William Short): Mr. Johnson, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Neil Johnson: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Mr. Glendining?

Mr. Murray Glendining: Yes, same.

The Clerk of the Committee (Mr. William Short): Same thing? Oath? Okay.

Mr. Glendining, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Murray Glendining: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Ms. Jansen?

Ms. Sandy Jansen: Yes.

The Clerk of the Committee (Mr. William Short): Same thing?

Ms. Sandy Jansen: Yes, please.

The Clerk of the Committee (Mr. William Short): Ms. Jansen, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Sandy Jansen: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

And last, Mr. LaRocca?

Mr. Tony LaRocca: Affirm, please.

The Clerk of the Committee (Mr. William Short): Affirm? Raise your right hand, please. Thank you.

Mr. LaRocca, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Tony LaRocca: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you all very much, and thank you very much for being here. With that, you will have 20 minutes to make a presentation, opening remarks, and you can make them in any order. Everyone or anyone can make that presentation. At the end of that, we'll have questions from the panel for 20 minutes from each caucus, and we will be starting with the official opposition. With that, the floor is yours.

Mr. Murray Glendining: Thank you. Good afternoon. My name is Murray Glendining. I'm the executive vice-president, corporate services and clinical support, and currently acting chief executive officer of the London Health Sciences Centre. I joined LHSC in June

of last year, and prior to that I was the executive vice-president of corporate affairs at Hamilton Health Sciences Centre.

Joining me today as requested by the committee are, to my immediate right: Neil Johnson, vice-president, cancer, renal and pharmacy services, at LHSC, and regional vice-president, Cancer Care Ontario. Neil is a pharmacist by training and has been with LHSC since 1988, progressing from staff pharmacist to director of pharmacy and through a range of executive responsibilities that included managing EDs, dialysis, medicine and neurosciences. Currently, Neil has a dual role with operational responsibility at LHSC for cancer, renal services and pharmacy services; and Cancer Care Ontario responsibilities that include implementing the Ontario cancer plan in the southwest region.

To my left is Sandy Jansen, director of pharmacy services at LHSC. Sandy is also a pharmacist and has been with LHSC since 2009, and became director of pharmacy in 2011. Prior to joining LHSC, Sandy held a variety of roles in pharmacy at St. Joseph's Health Care in London, progressing from a clinical pharmacist in clinical care to a variety of leadership roles in operations and medication safety.

On my extreme right is Toby O'Hara. Toby is the general manager, health care materials management services. Finally, on my extreme left is Tony LaRocca, our vice-president, community and stakeholder relations, responsible for communications at LHSC.

I would like to open with a few remarks for the committee, after which I will turn to Neil and Sandy to provide you with more information on our response to this issue from a clinical, pharmacy and patient perspective.

First, on behalf of this team and LHSC, let me extend our sincerest apologies to all of the patients and families who were affected by this unfortunate and unsettling issue. We know it has caused them a great deal of stress and anxiety, and, in many cases, has shaken their trust in our organization and in the health system. It is our goal, through close collaboration with all stakeholders and active support of the review process led by Dr. Thiessen, to help rebuild their trust by ensuring that all appropriate safeguards are in place for the patients we serve.

For context, LHSC is one of Canada's largest acute care academic health sciences centres. It provides the broadest range of services in Ontario. Our nearly 10,000 staff and physicians care for the most medically complex and critically ill patients across southwestern Ontario, with more than one million patient visits each year, including 150,000 emergency visits.

At LHSC, two key areas of focus are: improving the patient and family experience and excellence in patient care, service and safety. Underpinning these is our culture as a learning organization, which we hope is clearly reflected in our approach to the chemotherapy compounding issue. Through open and transparent communication, dialogue and collaboration with all system partners, and early and ongoing engagement of patients

to help us shape our response, we are committed to being a meaningful partner in rebuilding systems safeguards and trust.

At each step of the process, our focus has been to do right by the patient and to let our action planning evolve from that. Our patient advisers have helped us tremendously throughout this issue and will continue to guide our interactions with impacted patients. The initiatives that we have implemented to connect impacted patients with the support and information they need has been quite successful in helping them to put the situation into context.

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Our focus now turns to process issues and working with the review currently under way to identify any opportunities to improve safeguards, both in-hospital and system-wide, to prevent recurrences.

I will now ask Neil Johnson to provide the committee with a brief chronology of some of the events that have transpired since this issue was discovered.

Mr. Neil Johnson: Thank you, Murray. Before I walk through the sequence of events, I think that a brief overview of our cancer program may be helpful for the committee.

The London Regional Cancer Program at LHSC is one of the largest cancer centres in Ontario. As a research and education-based centre, we have a long history of innovation and research. Today, our centre sees over 7,000 new cancer patients each year, with over 180,000 patient visits to our centre. To put that in perspective, each day that we're open, we see, on average, 28 new cancer patients, and 720 patients visit our centre. With these volumes, it becomes apparent why the chemotherapy dosage issue we are reviewing today impacted so many patients at our hospital.

We first learned of the possibility of this chemotherapy medication issue on Friday, March 22, at approximately 2:30 p.m., when the hospital was contacted by Lakeridge Health and advised of a potential issue. This information was relayed to our director of pharmacy, who immediately initiated steps to have the cyclophosphamide and gemcitabine compounded by Marchese pulled from use. Although the complete magnitude and the facts were not clear at that time, the pharmacy team acted to ensure that no products were available in our organization to use. This action was completed at approximately 3:45 p.m., thus immediately preventing any potential further risk to patients.

Our team also started to reach out to make contact with the medication supplier to obtain procedural information on product preparation. I became involved shortly afterwards as I was completing meetings out of town. Our director of pharmacy notified our group purchasing organization, Medbuy, and was able to speak to a staff member who indicated that she would review her records to see who was purchasing product from Marchese and to notify these organizations.

Over the next few days, our investigation deepened and included a review of LHSC's purchase history. It

was determined that Marchese was awarded the contract to provide compounded IV services to Medbuy hospitals in late fall 2011. Through the Medbuy contract with Marchese, the London Regional Cancer Program began purchasing cyclophosphamide and gemcitabine on March 1, 2012, and the LHSC in-patient pharmacy began purchasing these products on October 15, 2012. Using these purchase dates, an initial data extraction of computerized patient records was commenced to identify patients potentially impacted. LHSC then undertook a number of other steps to begin to better understand the nature and extent of the problem.

To determine that the problem did not predate the start of the Marchese contract, the previous external supplier of these medications, Baxter, was contacted to obtain procedural information on product preparation. It was determined that products had been appropriately compounded. In parallel, we also reviewed Marchese's request-for-proposal submission.

LHSC completed an internal assessment of the Marchese chemotherapy medications by withdrawing all of the fluid of some of the medication bags on hand and measuring that volume. Three bags of each medication were drained and the fluid was measured. They were found to contain an average overfill of 11%.

By March 26, the potential magnitude of this issue was becoming increasingly clear, leading to the initiation of a full incident management team, which convened the following day. At the initial meeting, it was decided to add the co-chairs of our LHSC cancer community advisory group—two patients—to the daily incident review calls to help inform our response and interaction with patients.

That day, calls were placed to leadership at Cancer Care Ontario to notify them of our findings and approach. As well, LHSC's pharmacy manager began to place calls to other regional hospitals, including Windsor, to advise them of the exact circumstances of the facts that we found.

Additional external notifications of the issue were provided to the Ontario College of Pharmacists, HealthPRO, and research colleagues, and a phone message was left with Health Canada, all in an effort to further escalate the matter and ensure that any additional partners in the system that could be impacted were made aware of the problem.

After the data pulled from our computer system was reconciled, the list of impacted patients was shared with respective clinical leaders, beginning in the evening of March 27 for our pediatric patients and the following day for all adult cancer patients and non-oncology patients. Clinical data was then pulled to enable detailed patient record reviews, a manual and very time-intensive process involving many hundreds of files.

In the afternoon of March 28, LHSC participated in a teleconference with Cancer Care Ontario and the Lakeridge and Windsor Regional hospitals to discuss the situation and consider an aligned communication plan that aimed to ensure that, to the extent possible, patients first heard about this issue from their own hospital.

LHSC developed such a plan to notify impacted patients and connect them to the supports and information that they would need, and then to communicate the issue more broadly to key constituents. Given that the greatest patient impact was at LHSC, it was clear that the best efforts to contact patients would take several days after the clinical patient record reviews were completed, and initial rollout plans centred around that timeline.

Also on March 28, LHSC sent a letter to Marchese, clearly articulating LHSC's concern and requesting a reply to questions posed. They acknowledged receipt of the email but provided no official response.

That evening, Marchese did send an email outlining their process for compounding to LHSC's director of pharmacy. A review of patient records ensued, the clinical staff working day and night over the next three days to retrieve all relevant clinical information required by our medical staff in the review of their patients.

On April 1, it was reported that Windsor Regional Hospital had begun to inform their patients. It was evident that this would accelerate broader public awareness before LHSC could effectively communicate with its larger volume of impacted patients. Work then began at LHSC to change our communications and response plans for patients.

While Windsor's position is understandable and puts their patients' interests in the forefront, it created a very unfortunate situation in London, where so many patients heard about the issue in the media first, causing major concern for a much larger group of cancer patients who had received chemotherapy treatment during the period in question, even though the vast majority of those patients were actually not affected.

On April 2, patient disclosure to active LHSC patients commenced. Supports such as toll-free phone lines for pediatric and adult patients and an external website were implemented. Throughout that day and the next, finalized letters were produced for known living patients. As well, attempts to reach all patients by phone were made to notify them of the supports available and the letters that they would receive in the coming days. We also responded to several media interviews that day.

As calls from patients were received, patients in emotional crisis were escalated to receive immediate attention from their clinical teams. Many medical oncologists contacted their patients directly. For deceased patients, best efforts were made to determine next-of-kin addresses, and specific letters were sent to them.

On April 8, 9 and 10, open forums were conducted in our organization, with over 300 patients and family members attending. The goal was to be open and transparent about everything that we knew and to answer any questions that they may have had, to the best of our ability. Each session included a detailed presentation to explain the specific preparation processes for chemotherapy and how we believed the overfill situation for the supplies received had impacted medication dosage.

As well, a review of the chronology of the issue was provided, and a presentation was made by our medical

oncology leaders to discuss clinical implications. Questions followed, and each of the sessions lasted several hours, until all patient questions were addressed to the best of our ability.

On April 9, as part of our due diligence practice, LHSC initiated a second review to ensure that all possible patient impacts were captured in the initial assessment. During this review, it was discovered that the chemotherapy medications may have been used in the in-patient setting earlier than initially believed. This resulted from an internal transfer of subject medications from the cancer program pharmacy to the in-patient pharmacy, which occurred before the in-patient area began purchasing these medications directly from the supplier.

An immediate review of records commenced, and a further 26 potentially impacted patients were identified. These patients were notified by our staff and physicians prior to the media announcement of this development on April 12. At this point, a final tally was completed. All told, 691 patients were affected by this issue, 40 of whom were pediatric patients.

On April 15, LHSC received a verbal report from the Quebec laboratory to which it had sent a sample of the affected Marchese cyclophosphamide product. The lab report confirmed LHSC's internal finding in relation to fluid overfill. The concentration of the medication was less than that of a properly reconstituted vial. Specifically, the concentration of cyclophosphamide was 17.5 milligrams per millilitre, versus the target—if prepared accurately—of 20 milligrams per millilitre.

Our focus is now working diligently with all stakeholders to review the situation and help safeguard the health care system to prevent any reoccurrence.

I'll now ask Sandy Jansen, our director of pharmacy services, to comment in more detail on our pharmacy processes.

Ms. Sandy Jansen: Thank you, Neil. Pharmacy services provided at LHSC are among the most comprehensive of any hospital in Canada. We employ nearly 250 people, and that includes 65 pharmacists and over 150 pharmacy technicians.

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Just to give you a sense of the types of volumes of medications that pass through our doors every year, annually our pharmacy department processes over two million medication orders and we dispense close to five million doses of medication every year. Within that five million doses, we dispense 18,000 bags of IV nutrition, 15,000 bags of chemotherapy to our in-patients, and over 600,000 doses of IV medications to our in-patients.

Chemotherapy doses are prepared in the pharmacy in two very distinct areas. For our outpatients or for our ambulatory patients, we have a specialized pharmacy located right within the London Regional Cancer Program. For our in-patients, we have a specialized pharmacy located on the adult oncology ward.

On any given day, our cancer program in the London Regional Cancer Program sees about 80 patients. They dispense upwards of 185 IV chemotherapy doses every day, and that equates to about 44,000 doses per year. On

the in-patient side, we dispense about 20 doses to adults and 20 doses to children, and that's for the children and the adults who are admitted into the hospital.

All of our pharmacists and pharmacy technicians undergo specialized training and certification before they're allowed to participate in the preparation and dispensing of chemotherapy.

How did LHSC come to use Marchese products? LHSC has utilized the services of Medbuy, which is a group purchasing organization, for many years. In the fall of 2011, Medbuy tendered a request for proposal for many products, and included in that request for proposal was IV compounding services. There was a resultant competition between three vendors, and Marchese was the eventual winner, and in March 2012 we began purchasing products from Marchese.

Since receiving this news of concern about the concentration of the chemotherapy products on March 22, 2013, what has LHSC done to ensure the safety of the medications that we're providing to our patients? I can tell you, as Neil mentioned, that we immediately stopped purchasing any IV compounded products from Marchese Pharmacy, and we brought all of those products in-house. They are now all prepared by LHSC pharmacy staff. We have added additional staffing and shifts to accommodate that workload, and I can tell you that we have not delayed or cancelled any treatments as a result of that shift of workload in-house.

In addition, we have implemented reconstitution checks on any stock solution volumes that we make. We also keep a running tally of volumes of these stock solutions so that we can determine how much was used versus how much theoretically should be left in the vial, and that tells us that if we ever were to have an overfill issue again, we would pick it up very quickly. As an added precaution, we've implemented an internal review of all of our compoundings—not just IV and parenteral agents but everything. We're looking at every single process to ensure that we have validated all the controls, the checks and the balances, that they're all in place and all solid.

Lastly, as an academic health sciences centre, we want to use this extremely unfortunate experience as a shared learning opportunity. We're engaging with our peer hospitals to have a conversation about this and to share best practices when it comes to managing chemotherapy in our hospitals.

Mr. Murray Glendinning: Thank you, Sandy. I hope we've provided the committee with a better understanding of the circumstances surrounding this entire matter. I would like to reinforce that LHSC is supportive of and actively collaborating with Dr. Thiessen's review and will continue to review all processes and procedures to ensure complete safety of operations based on our learnings and this review process.

Our team will be pleased to answer any questions you may have to the best of our ability.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. With that, we'll start with Ms. Elliott.

Mrs. Christine Elliott: Thank you very much for appearing today. You were talking about checking with the previous supplier, with Baxter. Can you tell me how long you had been using these compounded solutions through Baxter and then making the change?

Ms. Sandy Jansen: I can answer that. We've been using Baxter CIVA centre. In 2004, we began purchasing a product from them. Over the years, our use of Baxter has grown. We started purchasing chemotherapy agents, specifically cyclophosphamide, in the fall of 2011.

Mrs. Christine Elliott: I'm sorry. In 2004, you were using the liquid solutions?

Ms. Sandy Jansen: We were purchasing pamidronate, which is another drug that's used within the hospital. Each of these companies has a large selection of things we can purchase, so we select from that.

Mrs. Christine Elliott: And then the RFP was issued in 2011. Can you tell me on what basis the decision was made to switch to Marchese?

Ms. Sandy Jansen: The RFP process took into consideration a number of things. There's a scoring built into an RFP. Things that were considered were quality of their products, their infection safety practices, their labelling, and their ability to supply us drugs in a timely manner. Cost was factored in, but cost was actually very low as far as a weighting—everything is weighted. At the end of the day, when all of the scoring was done, Marchese scored the highest, and that's why they won.

Mrs. Christine Elliott: Was there an internal discussion about that at London Health Sciences Centre before the decision was made, or did Medbuy just come back and say, "This is the one that we recommend"? Did you just go with that recommendation or was there an internal discussion? Because you had been dealing with Baxter, I'm just wondering if there was some concern about switching from Baxter to Marchese.

Ms. Sandy Jansen: No, there was no concern at the time of switching from Baxter to Marchese. All of the due diligence had taken place in the RFP process, and we felt that it was appropriate at that point to switch to the winner of the contract.

Mrs. Christine Elliott: You mentioned that the compounding process was sent by Marchese once it was determined that there was a concern about it. First of all, what did you think of the compounding process as it was explained to you, and secondly, had you ever seen it before?

Ms. Sandy Jansen: Overfill in mini-bags is something that we're very aware of in health care. So when we learned about the oversight of not withdrawing the additional overfill from the bag, it explained everything to us, essentially. We understood that they didn't take out that overfill, and I was alarmed by that.

Mrs. Christine Elliott: They didn't take out the overfill—that would have been Marchese?

Ms. Sandy Jansen: That's right.

Mrs. Christine Elliott: Okay. And they had not explained to you that they had overfilled or explained their process before that?

Ms. Sandy Jansen: No; not before that.

Mrs. Christine Elliott: So you were really just relying on the fact that you were getting a bag of product that was ready to use that didn't have to be changed in any way once it came into your hands.

Ms. Sandy Jansen: The bag was labelled with the exact concentration—4 grams in 200 millilitres—so that is the concentration that we used to base our dosing on.

Mrs. Christine Elliott: Okay. You also mentioned that you've changed your process now for quality assurance and you said that you would now be able to determine if there was any problem with the process. Could you just explain a little bit more about how that would work?

Ms. Sandy Jansen: The two drugs that are in question are actually the only two drugs that are available now as powder; everything else comes to us as liquid. It's very important that when we add liquid to that powder to mix it up and make it into a liquid, that concentration is perfect—exactly what we think it's going to be. As we then withdraw from that vial, we can see that we've drawn out 20 ml, 30 ml, 40 ml, and we can account for how much volume is left in that vial.

Mrs. Christine Elliott: When you first found out about the problem, you indicated that you stopped using the Marchese products. Were you dealing with any other company that was providing prefilled solutions, or did you just switch immediately at that point to compounding in-house?

Ms. Sandy Jansen: That's right. We were only dealing with Marchese for IV compounded products, and we just moved everything in-house at that point.

Mrs. Christine Elliott: Could you tell us a little bit about any interactions you've had with Dr. Thiessen or his group so far, please?

Mr. Neil Johnson: I can start. We had Dr. Thiessen on site for an entire day a week or so ago. He reviewed all of our processes and the chronology. We provided him with detailed information. He has toured each one of our pharmacy areas and met our staff and met our physicians that were involved in the response to this. I think the review process that he engaged—very thoughtful questions, very insightful questions and very appropriate. I think our team is very impressed with his oversight so far.

Mrs. Christine Elliott: It's pretty clear that your view is that it was Marchese that was the problem, not London Health Sciences Centre. Have you had any conversations with anyone there about this whole incident or problem once you reviewed their compounding process and discovered that it wasn't what you thought it was? Can you tell me about any interactions you've had with Marchese?

Mr. Neil Johnson: Maybe I can start. It's important to understand that when March 22 hit for us, unlike some of the other hospitals, we really didn't know exactly what was going on. We heard that there was an individual potential concern, and we spent those next number of days trying to discern what that actual concern was.

There was some initial conversation, as I understand, between our staff and their staff.

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We wanted to verbally understand what their processes were, because we really had no idea what the issue was. Then we tried to dissect: Is this something that's changed, is this a process they have had going on for a number of months, is this one individual? It wasn't until later on, as I've mentioned in my notes, that we actually received their full process for how they make them.

I think we did send a letter to them on the date I indicated in my opening statement, and we haven't received anything back from them—I don't know, Sandy, if you have received any other communication from them. They were, I think, free in giving their information. I don't think our team detected any hesitancy in providing factual information. Sandy, you may be able to clarify.

Ms. Sandy Jansen: No, I can say that when we spoke to Marchese to try to validate how they were making this product, they were very open and transparent with the information they were providing to us, and it was just through our interpretation that we understood the issue.

Mrs. Christine Elliott: Did they say anything to you about feeling that it was your responsibility to have done something other than to have anticipated that the product was exactly as it was stated to be?

Ms. Sandy Jansen: No. They didn't say anything like that to me personally.

Mrs. Christine Elliott: So you haven't really had any pushback from them, I guess, with respect to this whole issue.

Ms. Sandy Jansen: No.

The Chair (Mr. Ernie Hardeman): Ms. Gélinas?

M^{me} France Gélinas: Thank you for coming. I would like to start my remarks by congratulating you on handling a difficult incident and handling it in a way that is as respectful to the people impacted as could have been, under the circumstances. I can see by your opening remarks and by what we've known so far that you really tried to reach out and be as reassuring and open with the people in London and the people affected, and I thank you for that.

My first series of questions will have to be kind of following what—the line of questioning she was following. So the timeline is, you were with Baxter, then the request for proposal went out and then a new provider, Marchese, came in. But then there is a delay between the time that Marchese got the contract and the time you started purchasing from them. What's with the gap in between?

Ms. Sandy Jansen: It just so happens that about the same time as the contract switchover, the drug shortage hit. When the Sandoz drug shortage hit, a lot of things were sidetracked, and the switching over to Marchese was one of the things that got sidetracked.

M^{me} France Gélinas: Okay, so because the pharmacy was busy attending someplace else, you continued with Baxter for that period of time?

Ms. Sandy Jansen: Yes, and some of the drugs needed to be shipped to Marchese. And with the short-

age, we didn't know if we even had those drugs. So there was a lot of balancing to figure out what was our supply and what could we get to Marchese.

M^{me} France Gélinas: Okay. So you continued using the chemo drugs that were coming from Baxter until things settled, and then you started the relationship with the new provider.

Bringing you back, when was the last time, except for now, that you did them in-house?

Ms. Sandy Jansen: That we did them in-house? For the chemotherapy agents, we did them in-house prior to October 2011, when we started using Baxter.

M^{me} France Gélinas: Okay. You were there in October 2011 and, I'm guessing, the request-for-proposal process that brought Baxter into the picture. What were the motivations for looking at Baxter coming in as a supplier, rather than—you have quite an elaborate pharmacy structure. Why?

Ms. Sandy Jansen: I can describe it to you: The process for reconstituting both cyclophosphamide and gemcitabine is quite complex. They're currently the only two molecules we purchase that are still in powder form. Everything else is now provided from the manufacturer in liquid form. Each of those vials takes four hours to dissolve. When we add liquid to a vial, it takes four hours to dissolve, and it requires that the pharmacy technician shakes it every 20 minutes.

In the London Regional Cancer Program, we could be using between 20 and 40 cyclophosphamide vials alone every single day, and that takes up an entire hood where we prepare the drugs. With the volume of patients we have coming through, we needed to be able to free up that space and capacity—both space and capacity of our staff—to focus on those other agents and allow Baxter and then Marchese to do that reconstitution for us.

M^{me} France Gélinas: So what has changed now in space and capacity, now that it is back in?

Ms. Sandy Jansen: What we've done is, we still have the same amount of space. We've added staff and we've added shifts, so we can now prepare drugs sort of longer throughout the day so that those vials are reconstituted and ready for use each day.

M^{me} France Gélinas: Why not have done that in 2011?

Ms. Sandy Jansen: Because we had Baxter, which is a reputable provider, and we felt very confident in the services that they were providing. We felt it was an effective and efficient way to do our business, to allow Baxter to reconstitute the vials for us and bring them in-house.

M^{me} France Gélinas: Did you have the same feeling when you went with Marchese, that they were a reputable and good company to work with?

Ms. Sandy Jansen: Yes, we did. We felt that Marchese was a reputable company to work with.

M^{me} France Gélinas: Did you know anything about a grey area of oversight?

Ms. Sandy Jansen: No. At that time, we did not know that.

M^{me} France Gélinas: When did you become aware of this?

Ms. Sandy Jansen: Of the grey area? After all of the events that have transpired, and the information that we've since received that Marchese Hospital Solutions is not accredited.

M^{me} France Gélinas: When you became aware that there was this grey area of oversight, and the people—the specific division fell into that grey area of oversight—did it give you cause for concern?

Ms. Sandy Jansen: Yes, it did.

M^{me} France Gélinas: How come?

Ms. Sandy Jansen: Well, I think LHSC prides itself on the quality of care that we provide to our patients, so we would never knowingly use a provider that is not licensed and isn't providing the same quality of care that we ourselves provide.

M^{me} France Gélinas: Is there a way that you could have known that you were dealing with a branch of Marchese that was unregulated?

Ms. Sandy Jansen: I think hindsight is 20/20. Yes, we could have gone on a website and looked. There would have to have been something to inspire us to be questioning it. We understood we had documentation from them that said they were accredited.

M^{me} France Gélinas: Basically, you had no reason to believe—is it in the practice of a hospital to go and check if the labs you're dealing with—you have so many providers—and not only you, but maybe somebody else—whether it be an X-ray clinic or a lab or pharmacy. Are you in the business of checking who is regulated and who is not?

Ms. Sandy Jansen: I'm going to defer that to Neil and Toby.

Mr. Toby O'Hara: Sure, I can take that. HMMS—that's where I'm general manager—oversees the procurement and sourcing on behalf of LHSC. What I can share is that we do the competitive bidding when we haven't outsourced that to a GPO. In cases where we've introduced a new vendor to the contract team or to the vendor file, and they're unfamiliar to us, it is in all cases a contractual requirement that they meet all legislation. If they're unfamiliar to us, then we typically would check to make sure there's a medical device licence in play or they're registered with Health Canada.

Just to clarify where we're coming from, it's HMMS that would oversee primarily the medical-surgical non-drug sourcing of LHSC.

M^{me} France Gélinas: Do you have the equivalent to you that oversees the drug sourcing?

Mr. Toby O'Hara: The decision for drug sourcing has been essentially outsourced to Medbuy, so Medbuy oversees all the drug sourcing for LHSC.

M^{me} France Gélinas: Okay. Was there a process to make sure that the oversight that you had put in place was carried on? Because you're a member of Medbuy, are you not?

Mr. Toby O'Hara: Correct. All of the terms and conditions, or the scope of services Medbuy provides on

LHSC's behalf is defined in that participation agreement between LHSC and Medbuy.

M^{me} France Gélinas: You also shared with us that you went back and reviewed the request for proposal that Marchese had put forward. I think it was you, Mr. Johnson, who told us that.

Mr. Neil Johnson: Yes.

M^{me} France Gélinas: When you did your review, was there anything there that could have led you to believe that they were operating in a grey area of oversight?

Mr. Neil Johnson: I'm just recalling—I don't believe so. It only became clear when we understood, through media reports, that the contract was with Marchese Hospital Solutions. If I'm recalling—and I'll ask Sandy to verify and make sure I have the correct facts here—it was Marchese Pharmacy that did the RFP, responded to the request for proposal. I understood afterwards, after the media announcements came out, that it was another corporate entity that was named. In the request for proposal, I don't believe—and I'll clarify it with Sandy—that there would be anything that would alert us to that fact.

Sandy, you may want to verify that.

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Ms. Sandy Jansen: That's correct. The RFP was answered. The company was described as Mazentco operating as Marchese Pharmacy, and the documentation around accreditation was all under Marchese Pharmacy.

M^{me} France Gélinas: The oversight that you talked about, that you make sure that you deal with a licence, due diligence has been done—you were dealing with a pharmacy, and pharmacies have oversight?

Mr. Neil Johnson: As per Medbuy policies. Medbuy—and this will be a question for them later on, obviously—has a set of policies and practices that would be similar to what Toby's group would have at HMMS. We would understand that that due diligence would have been checked and appropriately dealt with.

Ms. Cindy Forster: Were you aware or did Medbuy make you aware that Marchese Pharmacy—that the business of compounding was new to their operations?

Ms. Sandy Jansen: No, I was not aware.

Ms. Cindy Forster: You weren't aware of that, and Medbuy didn't make you aware, or it wasn't part of their due diligence in the process when they're going out around new RFPs?

Ms. Sandy Jansen: I would defer to Medbuy to speak to their due diligence process. Our understanding was that Marchese had been in the business of compounding prior to Medbuy contracting with them, but I'll probably defer to Medbuy for that.

Mr. Murray Glendining: I think within any group purchasing organization, they confirm to us each year that they do comply with procurement guidelines, and so they attest back to us—whether it's Plexxus, whether it's Medbuy, they all confirm to us each year that they have followed standard business practices and procurement protocols, and we do rely on that.

Ms. Cindy Forster: You said that part of your reason for outsourcing these two particular drugs was efficiency and effectiveness. You didn't say anything about actual financial efficiencies, so did you actually save any money in the process of outsourcing this work?

Ms. Sandy Jansen: No. Outsourcing these two agents was not in any way an effort to save money. It was absolutely around efficiency and around safety and volumes.

Ms. Cindy Forster: How many staff FTEs did you have to actually hire to bring this back in-house?

Ms. Sandy Jansen: Right now, we're still in the hiring process, and we have people working overtime right now to do this. We're probably going to be looking at between seven to 10 additional pharmacy technicians at the end of the day.

Ms. Cindy Forster: Thank you. That's all I've got.

M^{me} France Gélinas: Coming back to the purchasing, had it been identified at the time that the corporate structure of Marchese included an unregulated arm, would you still have gone ahead, or would the procurement process in place—would that be a showstopper?

Mr. Neil Johnson: I would believe it would be a showstopper for me.

M^{me} France Gélinas: Same with you? It wouldn't have gone. A hospital deals with hundreds of outside suppliers of all kinds. There's a role to play for the provincial government, there's a role to play for Health Canada and there's a role to play for the hospital. There's a role to play for all of those players, if you want, in the health care system.

I tend to believe that the role of the government is oversight. We've put in place the college system, the College of Pharmacy, and the College of Pharmacy is the one that makes sure that pharmacies in Ontario are regulated, and pharmacists, as well as pharmacy technicians. Do you figure this is a good role for the Ministry of Health, to be the overseer?

Mr. Neil Johnson: Overseer of compounding pharmacies specifically or—

M^{me} France Gélinas: No. Overseer of the different agencies in the health care system.

Mr. Neil Johnson: I'm sorry. I'm not quite—maybe you could restate your question.

M^{me} France Gélinas: Okay. Within the health care system, there are hospitals, there are pharmacies, there are labs—there are a number of what we will call players in the health care system. A hospital interacts with most of them just because of the type of work that you do. The government oversees hospitals. They oversee labs. They oversee pharmacies. They oversee 27 different health care professionals. Is this a good role?

Mr. Neil Johnson: I can speak generally that I think oversight—and assuredness of products and competencies of various professional groups—is absolutely needed. Jurisdictionally, that might be the issue between Health Canada and the federal government and the provincial government in this particular grey area. I think there is a role for government and oversight of those in broad brush strokes. Specifically down to individual

areas, that would probably be beyond my knowledge to comment on that. But we need, as a hospital, as an organization, assuredness that we have high-quality products and services coming into our organization. There's an existing framework and network to assure that in a variety of fashions, including procurement. Any place where there may be an issue of where there's a gap that, for our purposes, needs to be closed, because we need to be assured that products and services that are on our door and go out to our patients meet the test of quality.

M^{me} France Gélinas: Do you ever see yourself, as a hospital, being responsible to oversee pharmacies or labs?

Mr. Neil Johnson: In terms of a regulatory framework?

M^{me} France Gélinas: Correct.

Mr. Neil Johnson: Again, probably out of my political background, but I don't see that. We are in the business of delivering services to our patients. Hospitals are not regulators, and you're talking right now about a large organization with a billion-dollar budget and 10,000 staff and thousands of physicians. You're also talking about hospitals that have 25 or 30 beds and far fewer staff, and so hospitals are very varied in practice and scope. Even the extent that we have taken, as an example, to do some investigation that we have, would be beyond the scope of many hospitals. Our role—and Murray, I invite your comment, or others on this—is to provide service.

M^{me} France Gélinas: I tend to agree with you, and that speaks to some of the concerns that the new draft regulations that the Ministry of Health is bringing forward are sort of a precedent where they're making hospitals responsible for oversight of community partners. I agree with what you just said. You're there to provide a service. Oversight needs to happen. You need to have confidence that the partners you're dealing with are—but I don't think it is your role, either.

We'll let it go around.

The Chair (Mr. Ernie Hardeman): That's all the time you have to answer to that question. Thank you.

Yes, Mr. Berardinetti.

Mr. Lorenzo Berardinetti: I wanted to welcome members from the London Health Sciences Centre for being here today. A lot of questions have been answered already, but just a very direct question, I guess: Has there been any increase in the rate of recurrence or death since these drugs were first administered? In other words, maybe it would be premature to ask this question, we're only going back several months—

Mr. Neil Johnson: I think to answer that question you'd need a full epidemiological study of that, much like actually our clinician scientists did in the post-Walkerton issue, as an example. There are no signals that would say one way or the other on that currently, at present. Our clinicians, who are also researchers, though, are interested in looking at that and following that cohort of patients. We've now got a set of patients and data in three or four centres that could be followed, but we can't

answer that question in the current construct. It would just be impossible to answer.

Mr. Lorenzo Berardinetti: Okay. Just to understand the process that you discussed earlier this afternoon: overfill, which is basically another word for dilution, means you take—you do this in-house now, so you basically take a pouch and mix it with a saline to create the drug that's then administered?

Ms. Sandy Jansen: I'm sorry. Can you repeat that?

Mr. Lorenzo Berardinetti: How does the process work? You're doing this in-house now, but again, and this is maybe just a hypothetical question, how do you think the underdosing occurred when you were administering this drug?

1500

Ms. Sandy Jansen: How did the underdosing occur when we were purchasing Marchese product? Is that your question?

Mr. Lorenzo Berardinetti: Yes.

Ms. Sandy Jansen: Okay. The process that Marchese used when they made these bags—I'll just walk you through it quickly. They took a 250 ml minibag. That bag, we know, contains between 3% and 20% overfill. So let's say that on average it would have 30 ml of extra saline in it. What Marchese did was they withdrew 50 ml to bring the total volume to what they read as 200 ml. In fact, that bag now had 230 ml, give or take, because it had overfill.

Then what they did is they withdrew essentially all of the bag, so they had to withdraw a further 200 ml from that bag to reconstitute two vials of drug. They reconstituted the two vials of drug—that means shake it up until it's in liquid. That 250 ml bag we started with would actually have had about 30 ml or two tablespoons full of saline left in it, so just a little bit of liquid, but it's there.

Then what they did was they took the two vials, withdrew the drug into syringes and put it back in that bag. So that bag—remember I said it had the extra 30 ml?

Mr. Lorenzo Berardinetti: Yes.

Ms. Sandy Jansen: It still has the extra 30 ml. Had they withdrawn the 30 ml and discarded that, like they did with the 50 ml at the beginning, everything would have been fine, because those two vials were exactly the right concentration. Because they didn't account for that extra volume, that diluted the drug.

When that comes in to LHSC, it's called a stock solution. That's a concentrated bag of drug. We don't administer that to a patient; we withdraw aliquots from that. So we might take out a gram or 20 ml of that bag. We withdraw that. That should have the exact amount of milligrams for the patient, but because it was diluted, it wouldn't have had exactly what we needed. But we wouldn't have known that.

Then we take that and put it into a smaller bag, and that's when we dilute it, ready to be administered to the patient. Does that make sense?

Mr. Lorenzo Berardinetti: Yes, that answers my question.

You also mentioned earlier that 691 patients were affected. So this diluted drug was administered to 691 patients.

Ms. Sandy Jansen: That's right.

Mr. Lorenzo Berardinetti: Since they have been affected, you've been keeping an eye on them to see if there's not going to be a long-term effect or health issue with them. And up to this point, to the best of your knowledge, there hasn't been any negative effect in those people we were talking about a few months ago.

Mr. Neil Johnson: That's correct. I was just talking with our head of medical oncology, and they reviewed their case files and haven't made any therapeutic changes to those patients' course of therapy.

I think it's also important to understand that the drugs that are used are part of a larger regimen. For chemotherapy, you'd typically have anywhere between two to five other drugs being administered as well. It's the aggregate synergistic effect of those medications that is treatment for patients.

Each one of those patients' individual case has been reviewed. They've met with all those individuals on an individual basis to review that with them. I think the largest piece clinically has been, actually, the emotional stress and strain and anxiety that this produces in patients who are affected. Also, every patient coming through our centre now has that potential to be thinking about this and not trust that system. So, outside of the clinical issue of their cancer, the emotional impact has probably been the largest thing we've been dealing with, quite frankly.

Mr. Lorenzo Berardinetti: Yes, and to reassure the patients who are coming to get treatment, you've been able not just to emotionally tell them, "Everything's fine," but you've been able to scientifically correct the product so that you're now administering the proper dose. Is that correct?

Mr. Neil Johnson: Yes, and we're going to be taking some other steps over the next months, in consultation with our patient advisers, to really be out front with our patients in trying to rebuild that trust in the overall system, certainly in our organization, but in the broader system as well, so that when somebody comes into our centre through the London Regional Cancer Program or our in-patient area, they can feel confident that we've taken the steps we need to, to make sure they're safe.

Mr. Lorenzo Berardinetti: Thank you. Those are our questions for now.

The Chair (Mr. Ernie Hardeman): Ms. McKenna?

Mrs. Jane McKenna: Thank you so much for being here today.

My first question is, is the London Health Sciences Centre's contract with Marchese? The contract that you have.

Mr. Neil Johnson: The contract is with Medbuy and Marchese, a member organization of Medbuy.

Mrs. Jane McKenna: So who wrote the contract? Medbuy?

Mr. Neil Johnson: Medbuy.

Mrs. Jane McKenna: So you didn't oversee any of that at all? It didn't go through you at all?

Mr. Neil Johnson: As I understand it—and Sandy can correct me if I'm wrong—there is a committee of pharmacy members from all of our member organizations that adjudicates these RFPs and provides input to that. The actual contractual process that's set out in the contract is Medbuy's purview.

Mrs. Jane McKenna: So then Medbuy's solely responsible for that contract that they have with Marchese?

Mr. Neil Johnson: For the contract. Once the pharmacy committee makes a recommendation on a vendor, I believe they do the contract. Am I correct?

Ms. Sandy Jansen: That's right.

Mrs. Jane McKenna: My next question is, do you find it odd that it took so long for anybody to notice this?

Mr. Neil Johnson: That's a question that we wrestle with daily. I know it's affected our pharmacy staff quite significantly. As a pharmacist, it's one of those things that you ask yourself: What could have been prevented? When you actually look at two bags side by side, visually you would never tell the difference between them. As you said, on a 100 ml bag you're talking about a teaspoon or two teaspoons of fluid. It's hard to determine that.

There are some process issues in our setting that are different. The large volume that we have means that we have multiple people working, and so seeing the various products side by side is something that they would never see. Also, if we finish use of one manufacturer's product and bring in another manufacturer, we don't actually have them in the same workplace at the same time, so they're not mixing individual product lines. Unlike, as I understand, the folks who found it, there was never that opportunity for us, that once-in-a-lifetime opportunity, to compare product because it would never be in the same spot at the same time.

Sandy, I don't know if there are other factors that you've come across, but it's one of the ones that we've all wrestled with over the last month.

Mrs. Jane McKenna: Thank God for the person who did have the opportunity to realize that there was a problem for all of the patients who have been impacted.

I just have one other question: Has this shaken your confidence now for outsourcing?

Mr. Neil Johnson: No, not for outsourcing. I think, having sat in front of 300 patients and explained to them the issues that were at hand, the thing that it shakes for me is trying to rebuild their trust in the overall system.

As we said, the products that we were getting from Baxter were of top quality before. We had confidence in them. We have other services that are provided, everything from lawn maintenance to other things that are very high quality. We need to focus in on what we're good at clinically, which is doing cancer surgery, cancer chemotherapy, cancer radiation therapy. But no, not in outsourcing as per se, if the right checks and balances and quality control are there.

Mrs. Jane McKenna: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. Mr. Yurek?

Mr. Jeff Yurek: Thank you for coming down. You do a wonderful job in our area of London and southwest Ontario.

A question going to the RFP: You said you had reviewed the RFP and one of the reasons Marchese was chosen was because of quality. What proof did they offer that they provided quality product?

Ms. Sandy Jansen: In the RFP response that Marchese provided to us, they did provide to us detailed descriptions of their sterility checking process. That was very well detailed in the RFP response. In addition, the committee compared their labels to the other proponents' labels and they felt that Marchese labels were more clear than the other proponents'. So those were the two factors that really caused Marchese to win, we understand.

Mr. Jeff Yurek: Was there any proof given of end-product testing at any time, batch testing to confirm concentration?

Ms. Sandy Jansen: No, they did sterility testing; they did not do concentration testing.

Mr. Jeff Yurek: You mentioned that the labelling was clear. The last hospital we had here last week stated that they didn't like the labelling; they preferred the Baxter labelling. What's the difference?

Ms. Sandy Jansen: The labelling that Marchese had in the RFP application was slightly different than what we actually saw when it came into the hospital.

Mr. Jeff Yurek: Did anyone hold them to task over the fact that—

Ms. Sandy Jansen: There was conversation that went back and forth, I understand, between Medbuy and Marchese. I think that Medbuy will be able to speak to that, and they were just getting that clarified with the labels. But in the original proposal, there was good clarification of the concentration—not just the concentration in total milligrams and total volume, but also concentration in milligrams per millilitre.

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Mr. Jeff Yurek: Back to the RFP question: You said that if you were inspired to question their accreditation, you would. Can you just elaborate more? In my world I live in, I think accreditation would have been front and foremost when I'm asking someone to give me a product to use in a hospital. Was that missed in the RFP? Just elaborate.

Ms. Sandy Jansen: No, I didn't mean to imply that we didn't ask about accreditation. Accreditation was a question in the RFP, and Marchese did state that they were accredited with the Ontario College of Pharmacists. So there was nothing to cause us to go back and say, "Are you sure you're accredited?" because we understood them to be accredited, and they provided us documentation of that.

Mr. Jeff Yurek: You said you have a participation agreement with LHSC and Medbuy. I can't officially ask for a copy of it—one of my colleagues can—but can we get a copy of that participation agreement for committee?

Mr. Murray Glendining: Yes, we can. We'll get you that.

Mr. Jeff Yurek: Okay. With that participation agreement, does the Ministry of Health give you any guidelines or standards that you must have when dealing with a third party outsourcer?

Mr. Toby O'Hara: I can speak to—there's legislation overseeing the procurement process.

Mr. Jeff Yurek: But that's the general broader public sector—

Mr. Toby O'Hara: Those are the general broader public sector guidelines; correct.

Mr. Jeff Yurek: Nothing directly with—

Mr. Toby O'Hara: Specific to drug sourcing—

Mr. Jeff Yurek: —drug sourcing—

Mr. Toby O'Hara: —I'm not aware of that, no.

Mr. Jeff Yurek: I found it interesting that HMMS seems to have quite a bit of guidelines in place for purchasing other product but when it comes to purchasing medication, especially—I'm going to say chemo medication right now because that's what we're dealing with. But I'm sure down the line there are going to be other medications out there that the Ministry of Health didn't really seem to have a role to ensure that those standards or guidelines are in place.

Mr. Neil Johnson: I think this one's a little bit different, if I may add, in the sense that drugs that we normally purchase are from Health Canada-approved organizations. They have a drug identification number and so forth, so the regulatory framework is there.

This RFP was actually a services contract, so to take X bag and X drug and compound them in a product that we could either use inside the pharmacy or inside the hospital. It's a services piece. That's maybe splitting hairs, but I think there are probably some learnings there in terms of how to adjudicate those types of RFPs.

Mr. Jeff Yurek: Is using blood products from the blood bank a service or a product? It's the same idea. You're taking a bag from point A and—

Mr. Neil Johnson: That one's a little bit different.

Mr. Jeff Yurek: —point B. You can answer me that later, get it to me.

Mr. Neil Johnson: Yes.

Mr. Jeff Yurek: That's my question. You get drugs from Health Canada oversight; you get blood products from oversight because of the blood scandal that we had years ago. The hips you buy are, I'm sure, coming from a certified, accredited oversight. But what got missed in the whole process was some sort of ensuring oversight over compounded medications. My concern is the Minister of Health missed the boat on that. Would you think it would be fair enough that it's an expectation that the hospitals themselves have to come up with the oversight? There are well over 150 hospitals—I don't know the true number—in this province, so we've got about 150 different standards and qualifications when we want a unified health care system. Do you not think that when we're going to outsource compounded medication, there should

be some sort of standard coming down from the Ministry of Health to ensure that it's done properly?

Mr. Murray Glendining: I think the attestation is a good first step, but we are looking for this whole review process to come up with regulations that are far broader and cover the situation far better than they have in the past.

Mr. Jeff Yurek: So there's a big lack in that area.

Do you know anything about the pre-qualification that went out with the vendors for the RFP to ensure that they could actually bid on the product?

Ms. Sandy Jansen: I have seen the questions that went out.

Mr. Jeff Yurek: Could we get a copy of that?

Ms. Sandy Jansen: I think Medbuy can provide that—

Mr. Jeff Yurek: Medbuy has them?

Ms. Sandy Jansen: Yes.

Mr. Jeff Yurek: Okay. Three vendors bid: Baxter, Marchese—who was the third?

Ms. Sandy Jansen: Gentès and Bolduc in Quebec.

Mr. Jeff Yurek: Just a question: Do you know much about them?

Ms. Sandy Jansen: I know a little bit about them.

Mr. Jeff Yurek: Are they a compounding pharmacy or they a manufacturer?

Ms. Sandy Jansen: They're, in my mind, similar to Baxter CIVA in that they're part of Galenova, which is a pharmaceutical manufacturer. They are licensed with the Quebec college of pharmacists, so there's some oversight there.

Mr. Jeff Yurek: How did you know they were licensed?

Ms. Sandy Jansen: Because I called them and asked them, and I got proof.

Mr. Jeff Yurek: Did you not get through to the OCP?

Ms. Sandy Jansen: Pardon me?

Mr. Jeff Yurek: Could you not get a hold of the Ontario College of Pharmacists, or have you tried?

Ms. Sandy Jansen: About Gentès and Bolduc? Well, I would need to go through their college.

Mr. Jeff Yurek: No, I mean if you had to call—the way you said it, it sounded like you had trouble getting through to the Ontario College of Pharmacists.

Ms. Sandy Jansen: No, no. At the OCP everything is online, so I can confirm accreditation there.

Mr. Jeff Yurek: A lot of my questions are for Medbuy. Do you guys have any more? We'll go around.

The Chair (Mr. Ernie Hardeman): Okay, we've just got a minute left. With that, I think we had another question from the government side. Ms. Mangat?

Mrs. Amrit Mangat: Thank you for being here today. My understanding is that the ministry recently introduced regulations with regards to off-site drug compounding. How will it impact your hospital practices?

Mr. Neil Johnson: The regulations?

Mrs. Amrit Mangat: Yes.

Mr. Neil Johnson: I think it would be too early to say. We have not reviewed them in detail. We've been

busy with this issue of dealing with the patients that we're serving right now. To be candid, I have not really looked at that in tremendous detail. That's my task this week, because I know they're coming up. I think in general, though, we would look for things that are comprehensive, but not onerous, in terms of the hospital sector.

Mrs. Amrit Mangat: And how about Health Canada's regulations? They have also recently introduced some regulations.

Mr. Neil Johnson: Again, Health Canada, the Ontario College of Pharmacists and the Ministry of Health—we have not looked at those in detail. The Ontario College of Pharmacists' one just hit my email as a practising or registered pharmacist on Friday, so I have not had the chance to go through them myself. I don't know, Sandy, if you've had a chance either.

Ms. Sandy Jansen: I have looked at each of the regulations, and again, as Murray said, I think they're an excellent first step. I think that we need to get a lot more clarity on them, though, to ensure that any grey areas are eliminated.

Mrs. Amrit Mangat: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. You have one minute left. Mr. Yurek?

Mr. Jeff Yurek: I'd love to use it. You've made mention of what you know about Marchese; you said they're reputable and Baxter is reputable. What made you think Marchese was reputable? What was out there that you didn't even worry about them being a—

Ms. Sandy Jansen: Marchese has been around for quite a while. Certainly, we've known of them in the pharmacy world and some of the work that they've done professionally to promote pharmacy and patient care. From that perspective, I thought them to be a very professional pharmacy and that dealing with them would be fine.

Mr. Jeff Yurek: That's it. Thanks, Chair.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Gélinas, you have a comment?

M^{me} France Gélinas: I just want to make sure it's on the record that we ask that you please table with the Clerk the RFP that was used. You mentioned that the RFP or the process included criteria used for the assessment of the three bidders, as well as weighting for the different criteria. If you could share the system of criteria, the assessment you used, the RFP itself, as well as the weighting and the participation agreement that you signed with Medbuy. If you could table that with the Clerk, that would be very useful.

The Chair (Mr. Ernie Hardeman): Thank you very much for that. With that, that concludes the inquisition. Thank you very much for being here. We look forward to the rest of our deliberations and coming up with a solution to the challenges.

Mrs. Christine Elliott: Mr. Chair, if I could, I would reiterate my colleague's request for a copy of the participation agreement between the hospital and Medbuy.

The Chair (Mr. Ernie Hardeman): Okay. Has everybody heard it?

M^{me} France Gélinas: Yes.

The Chair (Mr. Ernie Hardeman): Thank you very much.

CANCER CARE ONTARIO

The Chair (Mr. Ernie Hardeman): Our next deputation is from Cancer Care Ontario. As you're getting settled at the table there, we welcome you and thank you very much for coming in. The Clerk will be swearing you in or affirming you in, whichever is your preference. We'll do that first, before we start the process. Thank you very much.

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The Clerk of the Committee (Mr. William Short): Hi, Dr. Sawka. You can have a seat. That's fine.

If you could just raise your right hand, please. Dr. Sawka, do you solemnly affirm that the evidence you shall give to the committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Dr. Carol Sawka: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much, and with that, as we do with the other deputations, you will have 20 minutes to make your opening remarks and your presentation. At the end of the 20 minutes, we will then have 20 minutes' opportunity for each of the caucuses to ask any questions they may have about the presentation. The questioning this time will start with the third party when we get to the delegation.

With that, thank you very much for coming in, and the floor is yours.

Dr. Carol Sawka: Good afternoon, and thank you for having me here today.

This issue is of deep concern to all of us. As a medical oncologist with over 25 years of experience in looking after patients with cancer, I know just how difficult it is to face a diagnosis of cancer, let alone hear that the treatment may have been compromised, so my thoughts and concerns are really with the patients and their families. It's clearly a responsibility for all of us to find out exactly what happened and to put into place everything necessary to ensure that it doesn't affect future patients and their families.

I wanted to begin by telling you, very briefly, a bit about me. As I mentioned, by training I am a medical oncologist. Beginning in 1985, I started my career at St Michael's Hospital. I moved to Sunnybrook's Odette Cancer Centre in 1988, where over the years I managed a variety of cancer types but in later years specialized in breast cancer.

After heading the division of medical oncology and hematology and the systemic treatment program at Sunnybrook and the cancer centre, in 1999 I was appointed vice-president of regional cancer services for Sunnybrook and the cancer centre. In that capacity, I oversaw the comprehensive cancer centre at Sunnybrook, and I

also was responsible for building a network of cancer care.

I continued in that role until February 2005, when I was appointed to my current role as vice-president of clinical programs and quality initiatives at Cancer Care Ontario.

In addition, I am a professor in the faculty of medicine in the departments of medicine of the Dalla Lana School of Public Health and the Institute of Health, Policy Management and Evaluation at the University of Toronto. I was also a member of the Ontario Wait Time Advisory Committee, and I sit on the board of directors of the Canadian Association of Provincial Cancer Agencies and the Canadian Partnership Against Cancer.

Some words about Cancer Care Ontario: CCO is an operational service agency of the Ministry of Health and we are governed by the Cancer Act. We are the government's chief adviser on cancer control services and the system through which these services are provided. Our mandate is to drive quality and continuous improvement in disease prevention and screening, the delivery of care and the patient experience, not only for cancer but for chronic kidney disease.

Specific to chemotherapy, we are responsible for developing and implementing a quality agenda, leveraging our regional cancer programs and partnerships and other clinical networks. CCO does not operate nor manage the hospitals that provide cancer control services. We do, however, have funding agreements with hospitals and other cancer care providers which link funding to a clinical accountability framework and mandate the delivery of system planning data to us.

I'd like to take a moment to tell you about Cancer Care Ontario's role in this issue. I understand that Michael Sherar, our president and CEO, addressed this in his remarks but I feel it's important to recap our work.

On Wednesday, March 27, CCO was notified about the issue by the London regional cancer centre. Immediately, we scheduled a conference call with the affected hospitals known at that time for the next day, to fully review the situation and determine next steps and the roles of each organization. Some time was needed to allow the hospitals to have their own incident management meetings internally prior to the group call.

On Thursday, March 28, in accordance with our MOU with the Ministry of Health, our communications team provided an overview of the issue with the information known at that time to senior officials at the communications and information branch.

That afternoon a conference call was held between CCO and representatives of each affected hospital—this includes regional vice-presidents, pharmacy staff, oncology leads and communication leads—to get more information and to establish appropriate next steps. Included in this call were CCO's provincial head of the Systemic Treatment Program and the clinical program manager.

During this call, we learned early perspectives about the error, the approximate number of impacted patients, operational disclosure plans being considered by each

hospital, and that one other jurisdiction was impacted, namely Horizon Health Network in New Brunswick. It was decided that a patient-first approach was most important.

We also received information from London that Marchese was not supplying cyclophosphamide and gemcitabine to other hospitals, but we sought independent verification of this and action was taken to understand the potential broader impact on all of the 77 systemic treatment hospitals in Ontario. This was to be done through CCO's regional vice-president network once a briefing note was completed to ensure the most recent and informed information was shared.

Between Good Friday and the end of day Saturday, all parties worked together to develop this information document. In addition, on Saturday, March 30, CCO was informed that the LHIN and hospital CEOs of the affected hospitals requested a meeting to update them on the issue, as well as their desire to brief the minister directly. CCO recommended that a joint LHIN-hospital CEO call be held on Monday, April 1.

On Easter Sunday, March 31, CCO provided the information document to senior officials at the Ministry of Health's communication branch, a summary of all knowledge gathered to date. That afternoon, CCO contacted its regional vice-presidents at the cancer programs across the province to call their attention to the issue and ask them to confirm that the issue didn't involve any of the systemic treatment hospitals within their regions. The document was also shared with each of the regions.

On Monday, April 1, CCO initiated and scheduled daily incident management meetings with the affected hospitals. Also on Monday, a conference call was held with affected LHIN and hospital CEOs to review the current state and agree on patient outreach. It was decided that patient outreach would be staggered to begin Tuesday through Thursday for Windsor, London, Peterborough and Lakeridge. Windsor advised that patient outreach had already commenced due to patient visits.

CCO advised the Ministry of Health's communications branch of this notification to ensure that they had current insight. CCO also made direct outreach to several parties, including Medbuy, Ontario College of Pharmacists, Health Canada, HealthPRO and Marchese Hospital Solutions. I do note that our messages were not returned from Marchese and Health Canada.

On Tuesday, April 2, CCO issued a press release and sent an advisory notice to all systemic treatment hospitals in the province. That same day, media engagement began.

On Wednesday, April 3, daily briefing calls were established with the Ministry of Health. A teleconference was also held with our systemic treatment program committee, who are the heads of medical oncology and the regional quality leads, to discuss the issue and provide guidance. Dr. Michael Sherar and I were also invited to meet with the Minister of Health to brief her and the deputy minister on the issue and our actions to date.

On Thursday, April 4, a call was held between CCO and Peterborough to gain further information on the

incident beyond what had already been communicated by each hospital.

By Friday, April 5, all regional vice-presidents confirmed that the current issue with gemcitabine and cyclophosphamide did not exist within the other 73 systemic treatment hospitals within their regions.

On Tuesday, April 9, we sent a communication to the systemic treatment hospitals asking them the following questions, with a request for response the next day:

(1) Does your facility prepare or administer chemotherapy IV admixtures?

(2) Have you reviewed the advisory that CCO sent on April 2, 2013—and the advisory was again attached.

(3) Have you reviewed how overfill is managed with the appropriate pharmacy and systemic treatment staff members at your facility?

Final confirmation from each hospital was received by 5 p.m. on Thursday, April 11, to confirm that they had reviewed how overfill is managed at their facilities. Confirmation of these responses was provided to the Ministry of Health.

On April 15, as an added step, CCO began making outreach to private chemotherapy providers to ensure that they were aware of the issue.

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Through all of this, I feel that the hospitals and CCO responded very well to what was obviously a very difficult situation. Our first priority was to ensure that the affected patients were notified, had the right information, and were offered the opportunity to visit with their oncologist. We also wanted to ensure that the drugs in question had been removed from the shelves, and this in fact was the case.

As soon as CCO learned of the issue, my team became actively involved, to work with the hospitals to ensure a patient-centred approach to this issue, and I'm confident in the work that was done and the actions that we took.

I'd like to address chemotherapy safety as a broader issue. The preparation and administration of chemotherapy is incredibly complex, and I think it's important to highlight the safety of chemotherapy treatment in Ontario.

As is the case with all interactions that involve human beings and technology and multiple hand-offs, there does exist a potential for error. So in our health care system, we all work together to place an emphasis on minimizing the risk of an error from happening and impacting the patient. Also, we encourage a positive culture of risk identification and solutions.

Typically when a problem happens, it's not one person's problem, it's a system problem, and we all take it very seriously and look to identify mitigating solutions.

You may have read or heard me quoted in the media these past few weeks, saying that although what has occurred is indeed incredibly unfortunate, it has occurred against a backdrop of what is essentially a very safe chemotherapy system in Ontario.

Why do I say this? Some of you will recall a tragic incident that occurred at an Alberta cancer institute in

August 2006. A 43-year-old woman died after inadvertently receiving an infusion of a chemotherapy drug called fluorouracil, given over four hours instead of four days. The cause of death, as determined by the coroner, was sequelae of fluorouracil toxicity.

Upon learning of the incident and reviewing the circumstances, the cancer institute leadership acted appropriately and immediately to implement a variety of actions to reduce the risk of recurrence. In addition, they quite appropriately got the Institute for Safe Medication Practices Canada to come in to provide external expertise and to undertake a root cause analysis of this incident.

Subsequent to this work, additional research was undertaken by the Canadian Patient Safety Institute, together with the Canadian Association of Provincial Cancer Agencies, the Institute for Safe Medication Practices Canada, and five provincial cancer agencies, including Cancer Care Ontario.

We were aware of this work as it was emerging. The final report was produced in 2010, and the report identified three themes of potential error, along with recommendations for their mitigation. The methodology here was not the actual observation of error but observation of facilities, to better understand where error might occur in these settings. The three themes of potential error were around infusion pumps, elastomeric or preprogrammed pumps; ordering and labelling; and pharmacy practices.

Why is this all relevant? Well, when that report was released, and even prior to the final report, our leadership teams at Cancer Care Ontario analyzed the findings to see whether there were learnings to be applied in Ontario. What we learned is that we're very well positioned in Ontario when it comes to chemotherapy safety. In fact, much of what came from that report was already well under way in Ontario.

We also took steps at that time to address all of the other recommendations, to further strengthen our system.

So I think we have external validation from a third party that the things that are important to introduce into a safe chemotherapy system are in place or well under way in Ontario.

Next, I'd like to address the organization of systemic treatment services and describe the way in which quality and safety expectations are embedded in these programs.

In Ontario, we have 14 regional cancer programs. They map almost completely to the LHIN boundaries. These regional cancer programs are the networks of stakeholders, health care professionals, hospitals and other organizations that are involved in cancer prevention and care within each of the LHINs. Each is led by a Cancer Care Ontario regional vice-president.

Each of these 14 regional cancer programs has a regional systemic treatment program. These programs are responsible for ensuring access to safe, high-quality systemic treatment according to best evidence. Within each of those programs, there are medical oncology leads and quality leads who meet regularly with our provincial program. In addition, the quality leads, along with nurses and pharmacists, formed a safety collaborative in 2011

that has since evolved into a regional quality and safety network. This meets regularly to discuss best practices and potential issues to continue to drive chemotherapy quality and safety in our province.

All of this regional work is supported by our provincial Systemic Treatment Program, which aims to improve equitable access to high-quality cancer care for all patients in Ontario. We do this by setting standards and guidelines for all systemic treatments, and it's important to note that all of our guidelines are produced by clinicians, with some backup.

The other thing I'd like to point out is that we also work with oncologists and other oncology professionals to actually make sure that these standards and new research change and improve practice. Not everything has an evidence base that is amenable to a guideline for development, but there are many situations where good practice exists across the province, and it's important that each of the regions share that best practice with one another. So we convene and facilitate opportunities for that to occur.

The Systemic Treatment Program overall is responsible for developing a quality agenda. It does this with input from the regional providers. This quality agenda spans the whole spectrum of chemotherapy.

We follow the corporate quality improvement cycle that uses a concept of gathering and developing the evidence, undertaking knowledge translation and exchange activities. We measure implementation and we plan for improvement. A strong focus on the development of a culture of safety has been a cornerstone for the program.

It's through this overall approach that Cancer Care Ontario has produced a number of guidelines focused on safety issues. Together with the 14 regional systemic treatment programs, a provincial plan for systemic treatment was issued in 2009. During this planning process, the need for additional guidelines was identified, and as they have been produced, they have become the work of the regional cancer programs as well.

This provincial plan represents the work of the dedicated clinical and administrative teams across the province engaged in interdisciplinary and collaborative activities, and it's a clear statement of everyone's commitment to quality and safety.

Our work spans end-to-end activities in chemotherapy within the cancer centres. This includes safe prescribing, safe dispensing and safe administration. I'll give you examples of the work we've done in each category. I understand that you've already received copies of these guidelines.

With respect to safe prescribing, one of the findings of the Canadian Patient Safety Institute was related to the issue of ordering chemotherapy. Chemotherapy regimens are complex, and using a computerized order entry system ensures standardized protocols are available and used by the doctors who prescribe it, by the pharmacists who prepare it and by the nurses who administer it. This is an area in which Ontario has led since 1996. In fact,

we were one of the first jurisdictions to adopt a computerized physician order entry system.

Working in conjunction with clinicians, Cancer Care Ontario developed its own computerized physician order entry system specifically for the chemotherapy situation. It's called the Oncology Patient Information System, or OPIS. It supports regimen-based prescribing, ordering and administering. This is very helpful because it eliminates the scenario where a harmful drug error can occur because of incorrect reading of handwriting or incorrect calculation of dosage. It also flags drug allergies, drug-drug interactions or drug-disease interactions when the medications are ordered, thus assisting clinicians in making the most appropriate clinical decisions at the point of care.

As a medical oncologist who started my time in practice with a little handbook of chemotherapy regimens in one side of my lab coat and a slide rule in the other to calculate the body surface area and the doses, after which I wrote down the prescription and handed it in to the pharmacist, I can attest that this system has really revolutionized the way in which physicians are conscious of safety issues and are protected against the error that inevitably occurs when handwritten orders are the norm.

Moving on to safe dispensing, the preparation of chemotherapy can be toxic to both the preparer, the deliverer and the patient if handled incorrectly, and we've developed guidelines for safe labelling, safe handling and safe administration of chemotherapy drugs.

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As an example, our safe labelling guidelines evolved from the recommendations presented by the ISMP root cause analysis, and these were also referenced in the CPSI report. But our recommendations are actually much more detailed than what was recommended in the CPSI report, and they include all of the necessary components and formatting of an intravenous chemotherapy label to maximize safe delivery and minimize errors. And like all of our other guidelines, we collected the evidence and struck an expert panel to review the evidence and supplement that with consensus opinion to derive these series of recommendations.

Lastly, in the area of safe delivery or administration of chemotherapy, we have a number of initiatives in place. We worked closely with the de Souza Institute to develop a training program for nurses to ensure that they have the necessary education and skills that are associated with safe delivery of chemotherapy, and they've all now become certified by their Canadian association.

We have also developed a drug formulary. This is used extensively by health care providers and the public. This contains more than 600 documents on the appropriate use of drugs in the cancer system and contains information on drugs, regimens and patient information sheets.

So these are just a few examples of chemotherapy safety initiatives happening throughout the province, and it's because of initiatives such as these that I can confidently say that Ontario has a safe chemotherapy system in place.

However, as this unfortunate incident has highlighted, there's always more to be done, and I am committed to working with you today and with Dr. Jake Thiessen in his review to ensure that we all continue to better our health care system. Patient care and safety is our number one priority, and we will support Dr. Thiessen in every way we can.

This review will be an important component of the goal of continuous quality improvement and ensuring the best possible care for patients—a goal we all share.

Thank you for your time.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. With that, we'll start the questioning with the third party.

M^{me} France Gélinas: Thank you so much for this presentation. It has certainly helped me.

I must say that I've always been a big fan of Cancer Care Ontario. I admire the work that you do. I marvel as to where we are at in Ontario with cancer services. We are one of the best in the world, and a big part of this is because of the fantastic work that CCO does each and every day. This is a part of our health care system we can all be proud of. You have developed the infrastructure, the structure. You look at quality in every part of cancer treatment, prevention and cancer care, and this is what brought us as a province to where we are.

The example that you have given us as to how in depth you go to ensure quality kind of reinforces this. No wonder we're so good. It's because of the work that you do. You put the framework in place. You have the resources. You deploy the resources to do all of that good work, and it pays off. We have an excellent health care system, an excellent cancer care system, and I thank you for this.

Then comes the question: How come we never looked—I'll exclude myself. How come you never looked at subcontracting of the preparation of those chemo drugs? How come it never hit the radar?

Dr. Carol Sawka: Traditionally, hospitals have compounded all of their chemotherapy drugs on site, within the pharmacy. Cancer Care Ontario has actually never been involved with the procurement of drugs or supplies within hospitals.

Within the development of our regional systemic treatment plan, the issue of whether off-site chemotherapy admixture was a good thing was raised. It came up in the context of the Canadian Patient Safety Institute study as well. In fact, there are some theoretical advantages to it in that it takes what is a pretty routine procedure out of a very busy and often chaotic pharmacy environment within a cancer centre, and it offers the opportunity for quality and safety checks.

Our team investigated whether there was any evidence to really support those theoretical advantages in the experience of others and wasn't able to come down one way or another: Is this a good thing or is this not a good thing? With discussion with the hospitals, it was agreed that what we would do is prepare a framework to help hospitals sort through potential risks and benefits of off-

site chemotherapy admixture facilities and that the final decision would be made by the hospital. And that's what we did.

M^{me} France Gélinas: So although the early evidence would lead you to think there was evidence that the process of outsourcing was actually going to bring benefits, when you double-checked, you could not replicate this?

Dr. Carol Sawka: Well, there wasn't anybody who had really studied it. There was a lot of anecdotal information that it was useful, but there wasn't any proper scientific study to examine before and after, for example, to determine whether there were safety issues that had been mitigated by having this done.

In theory, the potential advantages are as I mentioned: the efficiencies of having a routine procedure done in a dedicated facility and the potential safety gains, as well as safety to the hospital personnel who are not equipped to deal with toxic chemicals.

On the risk side, there was the need to ensure the quality of the product and the need to ensure that the drugs in question had a long enough stability to allow for them to be transferred from the compounding facility to the cancer centre.

M^{me} France Gélinas: And that proved inconclusive as in one or the other was just as good, or you just didn't know about the outsourced one?

Dr. Carol Sawka: There was no real evidence one way or the other to say that on balance the risks outweighed the benefits. It was left to each hospital to try to determine whether, in their circumstances, they had the opportunity for outsourcing and to make sure that they understood the potential risks and benefits of outsourcing.

M^{me} France Gélinas: I'm guessing you have followed this issue just as much as everybody else. Did you know anything about a grey area of oversight?

Dr. Carol Sawka: I did not.

M^{me} France Gélinas: Did it surprise you?

Dr. Carol Sawka: The issue of procurement of drugs and supplies is not something that Cancer Care Ontario has been involved with. Our work to date has begun from the time the drugs and supplies are within the cancer centre, and we work primarily with the providers and the hospitals in question about the process of care that I described.

What this issue highlighted, though, is the fact that there is work to be done in this area, and that's why we're very committed to working with Dr. Thiessen in his review, because, to date, there has been no role for Cancer Care Ontario in this area, but we're very interested to work with Dr. Thiessen.

M^{me} France Gélinas: Can you see a future role for CCO in procurement?

Dr. Carol Sawka: I wouldn't like to speculate on that. I think we're very committed to working with Dr. Thiessen and understanding the recommendations. Of course, we're all very committed to putting into place what's necessary to ensure this doesn't happen again.

We're working very closely on the working committee to assist Dr. Thiessen in his review.

M^{me} France Gélinas: It is still surprising to me, because CCO deals with drugs a lot, through the committee to evaluate drugs and with all of the new protocols that come in. You guys play a huge role. A lot of the drugs that are now on the formulary are because of the work that you have done. So you do have an interaction with drug manufacturers and drug compounding agencies all the time.

Dr. Carol Sawka: We don't have interaction with compounding agencies. I would say that our interactions with the ministry are around making recommendations around which drugs should be added to the formulary on the basis of effectiveness and cost-effectiveness. We then administer the reimbursement program for a certain formulary of expensive drugs. It's called the New Drug Funding Program. In none of that work have we assumed a procurement role or a procurement oversight role. Each of us has a responsibility in the cancer system. The hospitals have their responsibility, the regulators have theirs, and CCO has had its mandate, which is to focus on the actual appropriate use of chemotherapy drugs and ensure that they're appropriately prescribed and handled within the system.

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M^{me} France Gélinas: But you also reimburse them. You give money to hospitals for them buying drugs without knowing where they buy them, how they procure them. You just pay.

Dr. Carol Sawka: Well, what we do with chemotherapy drugs is no different from any other element of what Cancer Care Ontario does in quality improvement. We make recommendations on cancer surgery without helping the hospitals procure the sutures and the surgical supplies. We make recommendations on appropriate use of pain medication to control symptoms and at end of life, but we don't actually get involved in the procurement of morphine or other narcotics. We make recommendations on pathology and how pathology reports should be formatted and completed, but we don't make recommendations or oversee the hospitals' purchase of the stains that are necessary to make their supplies. Traditionally, we each have a role to play and Cancer Care Ontario has not been involved in the procurement side of the equation. Our work, as I said, starts with the assumption that the supplies and drugs are as advertised and as purchased. If Dr. Thiessen's report suggests that there is something different that should occur in the future, of course we're very interested to hear the results of that.

M^{me} France Gélinas: Actually, I fully agree with you: Everybody has a role to play. I would say that the role of oversight, whether the compounding facility is regulated or not, falls within the Ministry of Health, not with you.

You mentioned something in the opening, that you also reached out to the private chemotherapy providers. Who are they?

Dr. Carol Sawka: The big providers are Provis and Bayshore. There are some smaller providers that provide

chemotherapy that is not funded on our publicly available formulary.

M^{me} France Gélinas: Okay. I didn't even know this existed; it's kind of a surprise. There are companies that will offer chemotherapy that are outside of the network of CCO?

Dr. Carol Sawka: Yes. Within Cancer Care Ontario, we have a formulary of drugs in the New Drug Funding Program that we're able to reimburse hospitals when they use them in accordance with eligibility criteria that have been established and agreed upon. If a patient and a physician decide that a particular drug might be useful in that situation and it's not on the formulary, a patient can obtain that drug through third party insurance or self-pay. These private infusion clinics have developed as a mechanism to deliver that type of chemotherapy.

M^{me} France Gélinas: Actually, I knew this. I just didn't realize this is what you were referring to.

I still stand by my opening comments: I have nothing but admiration for CCO. I find that what has just happened has sort of taken your name where it should have never gone. Cancer Care Ontario does provide excellent, quality care and should continue to do so. I don't know if it's a fair question, and you're allowed not to answer if you don't want to, but how damaging has this issue been to the work you're trying to do?

Dr. Carol Sawka: I believe that the public needs to have its trust and confidence restored in the safety of the cancer system. And that's the work that we're doing, right? The remarks that I made today are really intended to reinforce the fact that this really unfortunate incident that we all wish had never happened occurred on a safe platform of chemotherapy delivery. We're all very interested in getting to the bottom of it. We all have some responsibility in ensuring that this never happens again.

M^{me} France Gélinas: When you look at the 14 different regions that you serve, some of them were not impacted at all on a direct basis, as in they never used the diluted drugs and none of their patients ever received any of the diluted drugs. Did the impact of trust go beyond the regions that have dispensed those drugs?

Dr. Carol Sawka: I can't speculate on that. We really supported the hospitals that were affected because our first concern was for the patients and the families. The hospitals have been very active in responding to the patients and families and having open meetings, and have been, I think, responding as effectively as they can to this situation.

It's important to remember that there are 40,000 patients each year who get chemotherapy in this province, and they make 300,000 visits to the cancer centres. So even though one incident is one too many, in context, patients and the public should have confidence in the safety of the chemotherapy system in the province.

M^{me} France Gélinas: I agree with you.

If you look at all of the partners that make it possible for CCO to do the great work that they do, are you worried that there are other partners that you trusted that may have grey areas of oversight?

Dr. Carol Sawka: In a culture of safety, vigilance is really important. Safety is everyone's business, and it's all of our responsibility to be constantly aware of the potential for error. That's our role, and that's every health care professional's role. While I am not immediately aware of any grey areas, one of the important roles that we play is keeping our eye on the system and leveraging all of our partnerships with health care providers and within all of the regions to identify potential new sources of error.

As I mentioned, the health care system is a complex system. It has a lot of moving parts, a lot of people, a lot of trade-offs, a lot of technology. And as much as we do to mitigate the sources of error, another important feature is being very vigilant when a new error crops up, immediately dealing with it and sharing that information so that no other parties will be affected by it.

M^{me} France Gélinas: Were you disappointed that one of your partners, London, was not as quick at identifying the diluted drugs as your other partners? Lakeridge and Peterborough identified it right away; London didn't.

Dr. Carol Sawka: The issue of timing of identification is best addressed by the hospitals in question. I do know that the technician in Peterborough should be congratulated for a pick-up and having this dealt with when it was dealt with.

M^{me} France Gélinas: Have you done that?

Dr. Carol Sawka: Yes, we have.

M^{me} France Gélinas: Thank you.

Do I have any minutes on the clock? I'm going to save my two minutes.

The Chair (Mr. Ernie Hardeman): Mr. Berardinetti.

Mr. Lorenzo Berardinetti: Thank you, Dr. Sawka, for your very thorough presentation today. I really appreciate it. It was very impressive and very thorough.

Toward the end of your presentation, you mentioned working with Dr. Jake Thiessen. The ministry has taken this action, and the minister has also announced the creation of a working group of which you are a part. Can you tell us what the role of the working group will be?

Dr. Carol Sawka: Our president and CEO, Dr. Michael Sherar, is a member of that working group, along with the other parties. Their work, to date, has been to support Dr. Thiessen to make sure that he has all the information that he needs, and they have also been working to ensure that things are in hand with respect to the current situation. We'll be receiving Dr. Thiessen's report, and we'll be deciding on responsibilities for action.

Mr. Lorenzo Berardinetti: How would you characterize your relationship with the ministry in responding to this issue?

Dr. Carol Sawka: All parties took this very, very seriously, and we couldn't have hoped for better co-operation with the hospitals, with the ministry, with everyone we contacted. We all wanted to better understand this and to put into place everything necessary to make sure it wouldn't happen again.

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Mr. Lorenzo Berardinetti: What role has Health Canada played in responding to this issue?

Dr. Carol Sawka: I'm sorry—what role?

Mr. Lorenzo Berardinetti: Yes. In responding to this issue, what role has Health Canada played? Have you been in contact with Health Canada at all?

Dr. Carol Sawka: We are not involved with regulation specifically, but I do understand that Health Canada and the Ontario College of Pharmacists were very active immediately on this situation.

Mr. Lorenzo Berardinetti: The ministry's proposed regulations for oversight—are you aware of the regulations?

Dr. Carol Sawka: Yes, I am.

Mr. Lorenzo Berardinetti: Do you think they're appropriate? Are there any comments you would like to make regarding those regulations?

Dr. Carol Sawka: The ministry announced its intention to ensure that there would be no gaps in oversight, effective immediately, and the steps that have been put into place appear to address that. The Ontario College of Pharmacists have some proposed regulations that are out for consultation, and we've just taken a look at those. We're aware of the Health Canada and ministry regulations as well.

Mr. Lorenzo Berardinetti: Those are all the questions that I have. I don't know if there's anyone else who has any questions from our side. We may save some time for later.

The Chair (Mr. Ernie Hardeman): To the opposition: Mr. Yurek.

Mr. Jeff Yurek: Thank you very much for coming. I also reiterate the great care that cancer patients receive in our province, and you're commended for what you do. Any of us here could probably say we've had family members or we ourselves have been affected by cancer, and great care has gone into it.

I just have a few questions for you. What role does the LHIN have in this process? You mentioned them in your statement, but that's pretty much the first I've heard of them in this whole debacle.

Dr. Carol Sawka: That question is best posed to the hospitals and the LHINs. I don't have any direct information on that.

Mr. Jeff Yurek: You've made note here in your statement—in the Improving the Safety of Ambulatory Intravenous Chemotherapy in Canada report—of one of the three potential errors with regard to labels. The bags coming from Marchese were labelled 4 grams and 250 ml. Do you consider that proper labelling in reducing errors?

Dr. Carol Sawka: Our labelling guidelines were made specifically for individual patient prescriptions, so I could speak to that. They contain patient identification, the chemotherapy drugs, the dose, the volume etc.

Mr. Jeff Yurek: The concentration?

Dr. Carol Sawka: The concentration; exactly. Our labelling guidelines weren't specifically designed for compounding facilities.

Mr. Jeff Yurek: Since the procurement of compounded chemotherapy medication started, have you thought of revising that? Did that ever come up in the various committees you've had, that maybe we need to take a look at how these bags are coming in and standardize the labelling across the province?

Dr. Carol Sawka: That's the work that Dr. Thiessen is doing.

Mr. Jeff Yurek: Just now.

Dr. Carol Sawka: Yes. As I said, I think that what we have done is we have ascertained in a survey to all 77 hospitals that they have policies and procedures in place to ensure that this overflow issue that was apparent in this situation has been dealt with. We're confident that the issue that was at play here doesn't exist in other chemotherapy preparation, but we're very interested to work with Dr. Thiessen and to understand whether there is any role for Cancer Care Ontario to play in the labelling arena.

Mr. Jeff Yurek: Last week, Lakeridge noted that they didn't like the labelling coming from Marchese. One of the reasons they believe Marchese won the contract was because they had bar-coding on the label. I thought it would be great to help with the data that's in the bag, and they said no; in fact, that was used to help inventory control. What are your thoughts on labelling to improve inventory control, whereas there's no concentration on the bag?

Dr. Carol Sawka: I'd refer back to our guidelines. The guidelines state what our experts in labelling recommended.

The issue of bar-coding as a means of patient identification has come up—to match the actual intravenous infusion with the patient. The issue of inventory control is something that would be more relevant within a hospital setting.

Mr. Jeff Yurek: Have you had a conversation with Medbuy with regard to your guidelines on medication, the labelling and such?

Dr. Carol Sawka: No. We do not have a relationship with purchasing organizations.

Mr. Jeff Yurek: I can see why you wouldn't get too involved with procurement, because you only deal with cancer drugs and kidney medications, when there's a whole spectrum of medications out there that could possibly be compounded and brought into the pharmacy, like biologics and such. Do you not think, perhaps, that oversight or standards or guidelines should come from the Ministry of Health and should be there to have a co-ordination of standardized care for bringing in compounded medications in this province?

Dr. Carol Sawka: I believe that that's what the independent review—

Mr. Jeff Yurek: That's what we're doing now.

Dr. Carol Sawka: —is intended to ascertain.

Mr. Jeff Yurek: Do you think that may have come up at one time or another over the last 15 years?

Dr. Carol Sawka: I am not able to speculate on that.

Mr. Jeff Yurek: You mentioned Bayshore providing infusion clinics. I don't know a lot about Bayshore, but I

know they originally started out as a nursing agency. Where do they get their medications for the infusion clinics?

Dr. Carol Sawka: We are not involved with the private infusion facilities. They are responsible for the procurement of their own drug supplies.

Mr. Jeff Yurek: So you don't have any oversight—

Dr. Carol Sawka: No, we have no oversight of private infusion clinics.

Mr. Jeff Yurek: But you're paying them to—

Dr. Carol Sawka: No—

Mr. Jeff Yurek: —the clinics.

Dr. Carol Sawka: The private infusion clinics are not paid for by Cancer Care Ontario or by the public taxpayer. They are paid for privately by patients, either through third party insurance or self-pay.

Mr. Jeff Yurek: And who oversees these clinics? Do you know, by chance?

Dr. Carol Sawka: No, I do not know.

Mr. Jeff Yurek: Interesting. You mentioned HealthPRO earlier today. Can you just give me an overview of what HealthPRO is, please?

Dr. Carol Sawka: HealthPRO is a group purchasing organization like Medbuy.

Mr. Jeff Yurek: Like Medbuy?

Dr. Carol Sawka: Yes.

Mr. Jeff Yurek: And have they been involved in this situation at all? Do they have Marchese getting meds through HealthPRO or—

Dr. Carol Sawka: Again, because we're not involved with procurement, I don't have any first-hand knowledge of the relationship of Marchese with Medbuy or HealthPRO.

Mr. Jeff Yurek: That's all right for now. Do you want to go, Christine?

Mrs. Christine Elliott: I do have a few questions. Thank you very much, Dr. Sawka, for appearing before the committee this afternoon. We really appreciate your input. I just have a few questions just to follow up from my colleague.

The first one was, when you were talking about how you had done an analysis of the issue of outsourcing the mixing of solutions, and you didn't come down one way or the other but had a list of risks and benefits, was that contained—is that something different, I should ask, from the guidelines that you've already provided to us?

Dr. Carol Sawka: Yes. There are many situations in cancer care where people ask the questions, "Is such and such the right thing to do?" or "Is such a treatment the right thing to do?" or "Is there one best way to do something?" So we do a review of the literature to see whether, in fact, there's enough that has been written on this subject to enable a careful analysis. If there is, then that's actually amenable to production of a guideline, which is a recommendation around doing it one way.

But there are many situations in health care where processes of care are best determined locally, because each hospital, and its relationship with its pharmacy and nurses, differs one to the next, so there isn't really one

best way to do things. In that situation, our job is really to bring people together to have them share information about how they're undertaking certain processes of care to enable people to learn from one another, because there are lots of good types of processes of care that are occurring that need to be shared so that people can learn from one another, but they're not amenable to the production of a guideline, which is a single recommendation: "You should do it this way."

Mrs. Christine Elliott: Is there an actual document, then, that outlines these risks and benefits that we could have a copy of?

Dr. Carol Sawka: There's a simple framework that was really put together at the request of the hospitals that I would undertake to provide, yes.

Mrs. Christine Elliott: That's great. Thank you.

Dr. Carol Sawka: You're welcome.

Mrs. Christine Elliott: We appreciate that.

And was that communicated to all of the hospitals that provide chemotherapy programs?

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Dr. Carol Sawka: Yes. The Regional Systemic Treatment Program leaders meet with our provincial leaders on a regular basis, on a monthly basis, so they have an order of business that they conduct. This issue was discussed, and it was agreed upon that the decision about outsourcing would be a local hospital decision.

Mrs. Christine Elliott: Just looking at your presentation, on page 2, just in the chronology of events, you indicated that there was a conference call on March 28 that was involving a number of people, including the Ministry of Health, and from then on, between the 28th and the 30th, it appears that the action that was taken was through Cancer Care Ontario. Was there any action that was being taken that you know of by the Ministry of Health?

Dr. Carol Sawka: We were working with the hospitals to collect all the information. We wanted to know the number of hospitals affected, how many patients were affected, what the notification plan would be. We undertook a facilitation role to bring the hospitals together to communicate most effectively. We did communicate again with the ministry on the Saturday, and then again on the Sunday, to keep them informed of the information as it was unfolding.

Mrs. Christine Elliott: Did the ministry then basically give Cancer Care Ontario the responsibility for doing this investigation and coordination?

Dr. Carol Sawka: Well, it's a shared responsibility. The hospitals are very grateful for having a coordinating body like Cancer Care Ontario to help facilitate their discussions and keep one another informed, and really, the hospitals, the ministry, Cancer Care Ontario—all of the parties—took it very seriously, and they did what they needed to do when they needed to do it.

Mrs. Christine Elliott: You also indicated, I think—it's on page 3 of your presentation—that you and Dr. Michael Sherar were invited to meet with the Minister of Health to brief her and the deputy minister. Did that meeting actually take place?

Dr. Carol Sawka: It did.

Mrs. Christine Elliott: And how long a meeting did you have with the minister?

Dr. Carol Sawka: An hour and a half.

Mrs. Christine Elliott: Until she was fully brought up to date with what was going on?

Dr. Carol Sawka: That's right.

Mrs. Christine Elliott: And approved of all the actions that Cancer Care Ontario was taking in terms of investigating this matter?

Dr. Carol Sawka: The minister was most interested in understanding from me, from a clinical perspective, how chemotherapy is prepared and the more specific issues around chemotherapy. There were many channels of communication going on simultaneously, and her interest was primarily in understanding, making sure she understood how chemotherapy was prepared and delivered to the cancer centres. And that's the information that I was able to provide her.

Mrs. Christine Elliott: On page 6, again, of your presentation, you indicated that safe labelling guidelines were created, and I guess my question to you would be, did Marchese conform to the safe labelling guidelines as you had indicated that they should be followed?

Dr. Carol Sawka: The safe labelling guidelines were really intended for preparation of chemotherapy drugs for specific patients within cancer centres. They weren't specifically designed for the specific scenario that we're in here, where Marchese was supplying bulk drug to a cancer centre that then further used the drug among several patients, and so whether—the guidelines really weren't intended for them; they were specifically designed for individual patient doses.

Mrs. Christine Elliott: I know we're far from completing our investigation of this issue on any level, but do you have any preliminary observations about what you think needs to be done; what areas we should be concentrating on, for example?

Dr. Carol Sawka: It would be premature for me to comment on that. I do know that all of the parties are working very closely together, taking it very seriously, and we all have an interest in making sure this never happens again.

Mrs. Christine Elliott: Thank you. Those are all my questions.

The Chair (Mr. Ernie Hardeman): Ms. McKenna.

Mrs. Jane McKenna: Does Cancer Care Ontario have any policies or guidelines with respect to outsourcing chemotherapy compounds for in-hospital use?

Dr. Carol Sawka: Cancer Care Ontario has not traditionally been involved in procurement of any drugs and supplies, regardless of whether they are secured directly from the manufacturer or through a compounding facility. Our mandate has started from the moment the drugs are actually in the facility, and we work with the providers from that point onward. Our work has really focused on those areas.

Hospitals are responsible for procurement, regardless of whether they're from manufacturers or compounding

facilities. But as I mentioned, we're working—we're very anxious to hear Dr. Thiessen's report because if there are any new suggested roles for Cancer Care Ontario, we'd obviously be very interested in working with the group.

Mrs. Jane McKenna: Okay. And do you have any plans to develop a policy or is it strictly a hospital administrative issue?

Dr. Carol Sawka: We're awaiting the result of Dr. Thiessen's inquiry. We need to have a solid set of recommendations that determines who needs to do what in this area. We all share a responsibility in making sure we have the safest chemotherapy system possible.

Mrs. Jane McKenna: Thank you. That's it's for me.

The Chair (Mr. Ernie Hardeman): Thank you. The third party, Ms. Forster.

Ms. Cindy Forster: Thank you for being here, Dr. Sawka. Just one question: I heard you talk about a report that you kind of developed around the outside procurement, its risks and advantages. Can we get a copy of that report? Could it be tabled with the Clerk?

Dr. Carol Sawka: There was no report per se. It was work that our programs staff undertook to review publications and to try to determine whether there was anything written on the subject. So there was no formal report issued.

Ms. Cindy Forster: It was just really discussion at committees or—

Dr. Carol Sawka: That's correct, yes.

Ms. Cindy Forster: Are there any minutes that kind of flowed out of that committee that we could have tabled with the Clerk?

Dr. Carol Sawka: Yes, we have minutes for all of our committees, and I can undertake to provide those.

Ms. Cindy Forster: Great. Thank you.

M^{me} France Gélinas: When you looked at this, did you look at it with a view of bulk preparation? Because this is what Marchese was doing.

Dr. Carol Sawka: I don't have the details in front of me, so I'd have to undertake to provide you with the minutes.

M^{me} France Gélinas: That's okay. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. The government, Ms. Mangat.

Mrs. Amrit Mangat: Thank you, Dr. Sawka, for being here today. You mentioned in your statement that you're working very closely with the de Souza Institute to develop programs for nurses who deliver chemotherapy. Can you throw some light—what kind of institute is this and what kind of programs are being developed with them?

Dr. Carol Sawka: Sure. The de Souza Institute is a facility that's located at Princess Margaret Hospital that provides training to oncology nurses, to cancer nurses. We all have a goal of ensuring that nurses who provide cancer care have the highest possible training and also are certified by the Canadian Association of Nurses in Oncology. We've undertaken a goal to ensure that all of our nurses are in that capacity.

It's difficult for nurses to acquire that training when they're working shift work and they're working in remote facilities. So the de Souza Institute has developed a combination of in-person and online training, and this has been very helpful to the nursing profession because it's enabled them to achieve the training necessary to then go on and get their CANO certification. It is a program that is also undertaking interprofessional education because of the potential for online training.

Mrs. Amrit Mangat: Thank you. Do I have time?

The Chair (Mr. Ernie Hardeman): Yes, go ahead.

Mrs. Amrit Mangat: What other quality assurance measures are in place to ensure the safety of cancer drugs in Ontario?

Dr. Carol Sawka: We've provided a whole set of guidelines, but in essence we have cancer leaders in each of the 14 regions who work with our provincial programs, and together they help us determine the priority for quality improvement. We then have a process whereby the provincial program works with clinicians to address those priorities, and the regional programs implement them. Together, the programs have tackled a whole variety of topics, as I already described, and are continuing to work together in the areas of quality, appropriateness of chemotherapy, ensuring that patients get the right drugs and don't get the wrong drugs, and also that they are located—that the drugs are given in the centres that are suitable for the type of chemotherapy that's being given.

I refer to the Regional Systemic Treatment Program provincial plan. That was a piece of work that was done to develop regional systemic treatment programs in each of the 14 regional cancer programs. We assisted by preparing a set of standards around chemotherapy delivery for levels of chemotherapy facilities that would be suitable to various complexities of chemotherapy. That was done to ensure that there was a good mechanism, an access, to all levels of complexity within each region, good lines of communication between the facilities, and the appropriate oncology professionals who were trained and suitable to provide the chemotherapy in each of the facilities.

That also described the infrastructure requirements that would be required for the provision of chemotherapy and the organizational elements that would contribute to that.

That's something where we've actually used all of those regional programs. As guidelines and standards and new processes of care become available, we embed them into that work.

Mrs. Amrit Mangat: So are you confident in the safety of the cancer drug supply in Ontario?

Dr. Carol Sawka: I'm confident of the chemotherapy program in Ontario.

Mrs. Amrit Mangat: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. The official opposition: Mr. Yurek? Everybody has had their time.

Thank you very much for participating this afternoon and coming in and enlightening us on how Cancer Care Ontario was involved.

Dr. Carol Sawka: Thank you.

The Chair (Mr. Ernie Hardeman): We are slightly ahead of time; all the time was not used by some participants. We will have to take a small recess until the last delegation comes in. This would be a great time for one of those official breaks.

The committee recessed from 1622 to 1632.

MARCHESE HEALTH CARE

The Chair (Mr. Ernie Hardeman): We call the meeting back to order. Our next presentation is Marchese Health Care. I believe they are here.

As with the others, we will ask first of all that the Clerk either swear or affirm you in for the testimony that you're about to give. So we'll turn it over to the Clerk.

The Clerk of the Committee (Mr. William Short): Ms. Zaffiro, is it? Did you want to be affirmed or swear an oath?

Ms. Marita Zaffiro: Certainly.

The Clerk of the Committee (Mr. William Short): Which one? Affirmed or an oath? Affirmed: You raise your right hand—

Ms. Marita Zaffiro: Affirmed is fine. Sure.

The Clerk of the Committee (Mr. William Short): If you could just raise your right hand, please.

Ms. Zaffiro, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Marita Zaffiro: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we will start the program. You have 20 minutes to make a presentation to address the issues that we're here dealing with today. At the end of the 20 minutes, we will have 20 minutes from each caucus to ask any questions of your presentation. The questions will start with the government side when we get to that time.

So with that, thank you very much for being here, and thank you very much for being here just a few minutes early so we can get started just a little ahead of time. We'll turn the floor over to you to make your presentation.

Ms. Marita Zaffiro: Thank you, Mr. Chairman. Can you hear me okay? Can you hear me?

Mr. Phil McNeely: Speak louder. You're too far away.

Ms. Marita Zaffiro: I will try. Okay, just let me know if I'm not loud enough.

My name is Marita Zaffiro, and I am a pharmacist and the president of Marchese Hospital Solutions and Marchese Health Care. I thank you for the opportunity of addressing your committee on behalf of Marchese.

First, let me say that my heart breaks for the patients and families trying to process and understand what they've been hearing. We are deeply distressed to learn that some patients did not receive our preparations in the manner we expected.

I also want to state that Marchese does not wish to point fingers or place blame for this unfortunate incident. We want to explain our role in the process and help this committee understand what happened in order to make sure it doesn't happen again.

In 1988, I left my job as a young executive to buy a storefront pharmacy in Hamilton. The store was owned by a family friend. I wanted to carry on his tradition of service and build a more patient-focused pharmacy. I am pleased to say that with the help of many others, I believe we've succeeded. Marchese is now a group of Ontario companies that have been in business for over 50 years. Jack Marchese started the pharmacy in Hamilton in 1962. We've grown substantially over the last 25 years. The Marchese companies now employ over 80 Ontarians, including 15 pharmacists and several registered pharmacy technicians.

I am proud of our company, of our staff and of our service to our community. We have a long track record of leadership and recognition in the profession and in the area in which we do business. We have received many awards for our work.

Marchese Health Care now operates three accredited community-based pharmacies in Hamilton, Kitchener and Mississauga. Our pharmacies deliver services to clients who live in diverse communities. We provide these services in more than 10 languages. There is also a home care services business which includes the supply of intravenous medications, infusion equipment and medical supplies for home care patients.

In early 2011, we were invited to enter into a competitive bidding process to supply intravenous preparations—what we call admixtures—to Medbuy Corp. member hospitals. We were awarded the contract and, as a result, we formed Marchese Hospital Solutions, or MHS, in late 2011. The contract was for the supply of intravenous drug preparations to a number of Ontario and New Brunswick hospitals. Among the admixtures were cyclophosphamide and gemcitabine, the two cancer drugs of concern.

MHS was created as a separate division to keep the operations of our community-based and home care pharmacies separate from our hospital admixtures supply business. It was not created to avoid any type of regulation. While MHS supplied admixtures directly to the hospitals' in-patient pharmacy departments, our contract was with Medbuy Corp. Medbuy is a hospital group purchasing organization.

To increase safety, efficiency and the benefits from economies of scale, Medbuy contracts with suppliers like MHS to supply many different products to member hospitals. These are typically hospitals for which formulation of IV admixtures in the hospital pharmacy is either impractical or uneconomic.

Safety is also a very important factor. Some hospitals may be reluctant to have their own pharmacists and technicians preparing chemotherapy drugs. The drugs themselves are potentially toxic to any person handling them improperly. Our MHS personnel are trained to handle chemotherapy drugs and prepare them safely, without exposing themselves to potentially harmful effects. MHS prepares the IV admixtures safely and efficiently in our state-of-the-art facility in Mississauga. They are all prepared under the supervision of an OCP-registered pharmacist, and always have been.

I would like to now clarify for this committee what MHS does to prepare the two chemotherapy admixtures.

We play an important but limited role in the supply chain for medical treatment. Before MHS does anything, manufacturers produce the drugs, the equipment, the IV bags, and the solutions we use to prepare our admixtures. By contract, we take drugs produced by licensed drug manufacturers and ensure that they are combined in a sterile condition. We then ensure timely delivery of the admixture bags to hospital in-patient pharmacies. We withdraw a volume of saline solution from a pre-filled IV bag. The withdrawn solution is then mixed with the powder form of the chemotherapy drug. The mixture or reconstituted solution is then injected back into the bag. To be clear, no additional fluid is added by MHS. As one of the witnesses from the Windsor hospital stated, it is generally known in our industry that pre-filled IV bags are overfilled to account for evaporation while they are in inventory. Overfill also addresses the issue of volume remaining in IV tubing. In fact, overfill was discussed between MHS and Medbuy.

It is important to understand that the labels we place on the IV bags describe the contents only. They do not provide instructions or directions for use. They cannot contain the name of a specific patient, as this is not known to us. We deliver the IV bags to hospital in-patient pharmacies. It is the hospital pharmacist who labels a bag for use in the hospital and dispenses the medication at the direction of the treating physician. Hospital staff administer the contents of the bag to individual patients.

The labelling of our admixtures was discussed in detail with Medbuy both during the RFP process and before any of our preparations were supplied to hospitals. We were told by Medbuy that one of the reasons our response to the RFP was successful was that Medbuy's review team regarded our labelling as superior to that of its previous contract supplier. Medbuy approved all MHS labels before any product was shipped.

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After we began to supply Medbuy hospitals in February 2012, we continued to have discussions with them and some of the hospitals. At all times our labels complied with Medbuy's requirements as specified in our contract or as amended at their request. Until this incident, no issue was raised by anyone that our chemotherapy drug labels were unclear. If Medbuy or the pharmacist at any hospital had identified any problem with our label, we would have addressed it immediately.

There are two types of labelled intravenous solutions provided by MHS under the Medbuy contract. First, there are concentration-specific solutions that contain a defined amount of drug and solution. The concentration of the drug, represented as milligram per ml, and the volume of the solution are specified on the bag label. Second, there are admixtures intended to be administered in their entirety to only one patient. These are non-concentration-specific solutions, and they contain a defined amount of drug. The amount of solution in a pre-filled bag is not measured to a precise volume. A variance in solution amount is not material in a non-concentration-specific bag because the patient receives the precise amount of the medication. Whether a particular patient receives slightly more saline solution, including the overfill I mentioned earlier, with the medication makes no difference.

Interruption.

The Chair (Mr. Ernie Hardeman): Go ahead.

Ms. Marita Zaffiro: Okay, thank you.

I would like to stress for the members that our contract with Medbuy required us to supply cyclophosphamide and gemcitabine preparations only in non-concentration-specific form. We were not told how the previous supplier of these two drugs prepared its IV bags—whether the bags were in concentration-specific or non-concentration-specific form—nor were we provided a copy of the previous supplier's labels. We supplied the type of product Medbuy requested with the labels they approved.

I now want to turn to some of the questions that have been raised about regulation of MHS. Our role, our quality controls and our boundaries of responsibility have always been known to Medbuy, the Ontario College of Pharmacists and Health Canada. Marchese's community pharmacies are regulated by the Ontario College of Pharmacists. Our home care business is accountable under contract to the community care access centre and ultimately the Ministry of Health. A number of companies similar to MHS have emerged in the Canadian medical supply landscape over the last few years. Government authorities have always been fully aware of our presence and of the kind of work we do.

MHS has never attempted to operate without regulatory control. I want this committee to know that before this issue arose, and indeed before we began to service this contract, we went both to the Ontario College of Pharmacists and to Health Canada to inquire about the appropriate regulatory approval. Both the College of Pharmacists and Health Canada declined to regulate MHS.

MHS also approached the New Brunswick Pharmaceutical Society about regulation in New Brunswick. They too declined to regulate.

Even though there was no specific regulation of our admixture preparation services, we still instituted the most stringent quality control measures we could devise. I have always been assured that our organization operated according to the highest levels of quality. It is a core value from which I would not deviate.

My entire career has been devoted to improving patient care. I have worked collaboratively with hospitals, home care providers and pharmacists, and I am deeply committed to preventing incidents like the one that brings us here. But regulation alone does not ensure best practices; training, strong quality controls, constantly reinforced corporate values, and a management that practises what it preaches can—that is how I have tried to build my company.

The committee heard from one witness that Health Canada is planning to regulate MHS and others. Health Canada will require that all admixtures are prepared under the direct supervision of a licensed pharmacist. This is what we have always done. The admixtures at issue were all prepared under the supervision of a licensed pharmacist.

I want to conclude by speaking about Marchese's response to the investigations as a result of this incident. We have spent countless hours responding to inquiries from Health Canada, the college, and the Ministry of Health and Long-Term Care. We have also met with Dr. Thiessen and are co-operating with him to the fullest extent. Health Canada, the Ontario College of Pharmacists and Dr. Thiessen have been given full access to our premises, our people and our processes. They are being provided with all of the documents they have requested. Dr. Thiessen has met with me and my employees. All of us have been and will continue to be open.

We want to prevent these types of incidents as much as anyone else involved. We remain committed to assisting in any way to improve patient care and confidence in our health care system. We are proud of the role that Marchese employees play every day in providing quality health care to thousands of citizens.

Thank you. I welcome the opportunity to respond to the committee's questions.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. And with that, we'll start the rotation. Mr. Berardinetti.

Mr. Lorenzo Berardinetti: Thank you for your presentation today. I'm going to ask you some questions on an information-gathering basis, I'm not here to cross-examine anybody. I just want to get information here today. So I thank you for being here.

Is the gentleman beside you your counsel?

Ms. Marita Zaffiro: Yes.

Mr. Dominic Clarke: Yes. My name is Dominic Clarke and I'm a partner with the law firm of Blaney McMurtry. I'm here as Ms. Zaffiro's counsel.

Mr. Lorenzo Berardinetti: All right; thank you. I'm going to just go to a quick question. What, in your opinion, do you think went wrong in this process?

Ms. Marita Zaffiro: I believe that it was a communication issue where there were expectations or assumptions. We, at no point, received the information to understand that what was desired by some hospitals—perhaps, not necessarily all—were concentration-specific products. These products were prepared and labelled accordingly in a non-concentration-specific manner, similar to many of the other admixtures that we prepare.

Mr. Lorenzo Berardinetti: So you say it was a communication issue. Can you just elaborate a bit on what that communication issue was?

Ms. Marita Zaffiro: The way products were specified were how they are basically described. A concentration-specific product request would have a specific concentration on the label or on the description of the product. That was not the case with these products. A non-concentration-specific product says something like "4 grams in a 100-ml bag." And so that does not mean absolutely 100 ml; that means "4 grams in a 100-ml bag, plus the overfill that the manufacturer includes in that bag." That's how these products were spec'd.

Mr. Lorenzo Berardinetti: Okay. You mentioned in your presentation that the labelling is usually the responsibility of the hospital or the pharmacist at the hospital.

Ms. Marita Zaffiro: The labelling is the key communication device. Our label set in its entirety was provided to Medbuy, and Medbuy used that to orient the hospital members to the products that we would be providing. That would've been an opportunity to identify that, because there are concentration-specific elements, these two were also concentration-specific. Given that the labels did not indicate that—if that's what they were looking for—that's where that might have happened. That did not happen at any time.

Mr. Lorenzo Berardinetti: So Marchese doesn't do labelling. Your company doesn't do the labelling.

Ms. Marita Zaffiro: We label the bags with the content and descriptions that Medbuy has asked us to do under contract. They approve our labelling.

Mr. Lorenzo Berardinetti: So you do that part, and then you provide it to the hospitals?

Ms. Marita Zaffiro: Right, and as I said, the hospitals label it with the patient name and deliver it to the floor where it's going to be administered.

Mr. Lorenzo Berardinetti: Excuse me; I wasn't sure about your answer there. So the labelling is done by the hospital regarding the patient—

Ms. Marita Zaffiro: Correct.

Mr. Lorenzo Berardinetti: —and what do they put on the label?

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Ms. Marita Zaffiro: Well, you'll have to ask them to confirm, but I believe that they would put the patient's name. They would indicate to infuse the contents over a period of time. Sometimes it's infused over 30 minutes, 60 minutes, etc.

They have other information. There are conventions that are recommended through ISMP for that purpose.

Mr. Lorenzo Berardinetti: Okay. So you provide some of the labelling, but the rest is done by the hospital or the pharmacy that gives it to the patient affected in this case.

Ms. Marita Zaffiro: Correct.

Mr. Lorenzo Berardinetti: If there were to be any problems with the system with regard to the process of delivering the product eventually to the patient, where do you think that problem may have happened?

Ms. Marita Zaffiro: Can you repeat the question? I'm sorry.

Mr. Lorenzo Berardinetti: I'm sorry. If there was a problem—let's say, you produce the drug. Is that correct? You produce the—

Ms. Marita Zaffiro: We produce an admixture, a preparation that mixes an active drug ingredient in a solution.

Mr. Lorenzo Berardinetti: So you compound whatever is required to be compounded, into a product that can be administered by a hospital.

Ms. Marita Zaffiro: That's correct. We compound admixtures. The understanding is that when you have a non-concentration-specific product, the entire contents would be delivered as a unit dose to one patient.

Mr. Lorenzo Berardinetti: Okay. And if there was a problem in the system—I don't want you to point fingers—where do you think that problem may have occurred?

Ms. Marita Zaffiro: I think that our best opportunity to really define that clearly and intelligently is through Dr. Thiessen's inquiry. He has the ability to ask the questions, to inspect the premises, to look at the processes and to really make an informed judgment on that, and the recommendations that will improve.

Mr. Lorenzo Berardinetti: So you are co-operating with Dr. Thiessen—

Ms. Marita Zaffiro: Absolutely.

Mr. Lorenzo Berardinetti: —and his group.

Ms. Marita Zaffiro: And his—

Mr. Lorenzo Berardinetti: And his group, the people that will be working with him.

Ms. Marita Zaffiro: Well, we're not part of his group, but we have spoken to him.

Mr. Lorenzo Berardinetti: Okay. I think there are some other members that want to ask a few questions, Mr. Chair.

The Chair (Mr. Ernie Hardeman): Okay. Go ahead.

Mrs. Amrit Mangat: Me?

The Chair (Mr. Ernie Hardeman): Ms. Mangat.

Mrs. Amrit Mangat: Okay, thank you, Chair.

How long have you been providing compounded chemotherapy drugs to hospitals in Canada?

Ms. Marita Zaffiro: In Canada? This contract began in February 2012, but Marchese as a group has been providing sterile intravenous admixtures on a per-patient basis to home care clients for almost 20 years.

Mrs. Amrit Mangat: Can you please take us through the process of compounding these medications?

Ms. Marita Zaffiro: Sure. I thought I said it in the statement, but I'll take you through it again.

If you have a non-concentration-specific product, it would mean one dose/one patient. You would take a sterile bag with a solution. It could be saline or it could be dextrose, and those are specified through either what the client would like or by the type of drug.

Sometimes, if it's non-specific, you could dissolve the drug in sterile water, depending on the requirements, and just put that into the bag without removing any volume.

Sometimes the drugs you put in are liquid, and you would just add that liquid and you would not take out a reciprocal amount.

Sometimes you would actually remove the diluent. If the diluent, say, was going to be saline, you would put that in the vial, mix it up, take it back out of the vial and put it in the bag.

At the end of the day, you would have the original 100-ml-labelled volume; the overfill, which is a known range in the industry, by manufacturer; whatever added volume you may have added to reconstitute the drug; and any volume displacement of the drug, which doesn't happen too often.

Mrs. Amrit Mangat: Who are your other competitors?

Ms. Marita Zaffiro: Who are my competitors in hospital solutions?

Mrs. Amrit Mangat: In compounding drugs.

Ms. Marita Zaffiro: Baxter, Calea; Bayshore does some. This is compounding generally, not just for hospitals. I don't know other people's, but I know that in the home care compounding there's Rexall and Desjardins.

Mrs. Amrit Mangat: Can you please explain to me, for my own information, how Marchese mixed chemo drugs differently from Baxter?

Ms. Marita Zaffiro: I don't absolutely have the information about what Baxter did or did not do. So that's difficult for me to say. I think that you need to ask the hospital that, because that's sort of the million-dollar question. If we understood that, or if we had some hint that that was the case, through either the labelling or the description of products requested, or because when we were reviewing the products—then we would know. If we needed to make a concentration-specific version, there are different ways that you can do that.

Mrs. Amrit Mangat: Okay. What is your relationship with Medbuy?

Ms. Marita Zaffiro: What is our relationship? We have a contract with Medbuy through Marchese Hospital Solutions.

Mrs. Amrit Mangat: Thank you.

Ms. Dipika Damerla: How much time do I have left, Chair?

The Chair (Mr. Ernie Hardeman): Oh, yes, go ahead.

Ms. Dipika Damerla: How much time do I have?

The Chair (Mr. Ernie Hardeman): You've got about 10 minutes yet.

Ms. Dipika Damerla: Okay.

Thank you so much. I'm just going to revisit the whole issue of concentration, because in my understanding, the simplistic term is, some patients got a diluted version of the drug. But the way I've understood it, it's a sealed bag—

Ms. Marita Zaffiro: Yes.

Ms. Dipika Damerla: —and it's got, say, 100 millilitres plus the overfill; I understand that. I don't know what the variation is, if it's 5% overfill or 2%. Then you put in four milligrams, just for an example, into that,

injected. Now, you say sometimes you pull out four milligrams—

Ms. Marita Zaffiro: That was a general—let me just be clear. On, say, gemcitabine, we actually take the diluent out of the bag. It's a substantial amount and it pretty much empties—it takes 100 mls to actually dissolve the two two-gram vials. So you take out a hundred, you put it back in, but you've left the overfill in there. Then that particular drug expands by about five more mls, so you would have the 100 mls, the expansion volume, and the overfill that was in the bag.

Ms. Dipika Damerla: But your labelling would say four milligrams of drug—

Ms. Marita Zaffiro: In—

Ms. Dipika Damerla: In 100 millilitres—

Ms. Marita Zaffiro: In 0.9% bag.

Ms. Dipika Damerla: —plus expansion?

Ms. Marita Zaffiro: No.

Ms. Dipika Damerla: No, so plus 100 millilitres.

So this is where the dilution would have occurred, then.

Ms. Marita Zaffiro: That's right. If that was a concentration-specific bag, first of all, we would remove the excess and it would be stated as a milligram-per-ml final solution.

Ms. Dipika Damerla: So you were not giving the hospital, or Medbuy or whoever it is, concentration-specific—

Ms. Marita Zaffiro: We were not, nor were we labelling it as such.

Ms. Dipika Damerla: But my understanding, then, just following through the story, is that for some reason some hospitals thought they were concentration-specific, and that's where the challenge occurred.

Ms. Marita Zaffiro: Yes, that's what I understand.

Ms. Dipika Damerla: Now, what does your contract say, with Medbuy? Does it say—

Ms. Marita Zaffiro: The contract describes these products as non-concentration-specific. There are no concentrations, i.e. milligram-per-ml terminology, in the contract, nor on the labels that they approved and oriented the hospitals to.

Ms. Dipika Damerla: So whose responsibility would it have been to tell the hospital pharmacist that these bags—that this labelling is not concentration-specific, so that they could be more diluted? Whose responsibility would that have been?

Ms. Marita Zaffiro: To tell them?

Ms. Dipika Damerla: Yes.

Ms. Marita Zaffiro: I don't know that I can say whose responsibility it would be to tell them.

Ms. Dipika Damerla: Because you were creating them, right? So—

Ms. Marita Zaffiro: We were creating them. Through the transition with Medbuy, we discussed the products, how they needed to be made, how they were labelled. They approved the labels. They brought the labels to the hospitals for their approval and orientation. My expectation was that the professionals all through the chain, the

pharmacists at Marchese, pharmacists at Medbuy, pharmacists in the hospital—my expectation is that all pharmacists through that chain would fulfill their responsibility in understanding what was being provided, understanding what the labels said and didn't say, using those products appropriately, and, if that was not acceptable, to identify that to us, and we would have created a new formulation for a different product that was a concentration-specific version of these drugs.

Ms. Dipika Damerla: Okay, so let me rephrase that: Is it common to have non-concentration-specific bags like this given to the hospital pharmacist?

Ms. Marita Zaffiro: It is very common. The majority of products that we make—antibiotics etc.—are made in a non-concentration-specific form, and they are labelled with that very same convention. It is much more unlikely to have a concentration-specific drug.

Ms. Dipika Damerla: But for some reason, some assumptions were made that these were concentration-specific drugs and that's how they were being administered. Would that be your understanding?

Ms. Marita Zaffiro: I would have to speculate that what they received previously might have been in that form if they actually purchased from another provider, but that would be pure speculation. We needed to work with the information we had and our consultation with Medbuy, and Medbuy pharmacists and the hospitals had the opportunity to see through the descriptors and the consistency of what was being provided, or what they could understand was being provided.

Ms. Dipika Damerla: Okay. Thank you very much.

The Chair (Mr. Ernie Hardeman): Thank you. We'll now go to the opposition. Ms. McKenna?

Mrs. Jane McKenna: Thank you so much, Ms. Zaffiro, for being here today.

My first question is this: Your contract is with Medbuy, and Medbuy is actually who wrote the contract, so they're solely responsible for that contract. So was your communication breakdown with Medbuy?

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Ms. Marita Zaffiro: I guess there are two points of communication: with us and Medbuy, and Medbuy and the hospitals.

Mrs. Jane McKenna: When the London Health Sciences Centre was here today, they said that they didn't oversee what was written in the contract. The contract was written by Medbuy, and the contract was between the two of you.

My next question is: London Health Sciences Centre, like I said, was here today and Sandy Jansen, the director of pharmacy services, mentioned that you were one of three on the short list, and when they got the label, that was the reason they decided to go with you, when they saw that with the RFP. But then when they received the label with the product, there was a question of the label was different. She said that she had spoken to Medbuy and I guess to yourselves to figure out what the difference was when they saw it in the short list and when they saw it with the product. Can you explain what the difference was?

Ms. Marita Zaffiro: I'm not sure what she's referring to. I do know that for gemcitabine, as the contract was beginning, it was identified that there was a slash used where the word "in" should be. London Health Sciences identified that, and that was clarified early in the process.

Mrs. Jane McKenna: So that was all rectified? That was cleared up—

Ms. Marita Zaffiro: Well, it was rectified, but it is—but it was clarified such that it said "in 100-m bag." So it didn't clarify to identify at that time that a concentration-specific product was being expected or assumed. But there was a conversation around that particular item.

Mrs. Jane McKenna: Okay. That seems like kind of it was a grey area there with her as well when she was—

Ms. Marita Zaffiro: Yes.

Mrs. Jane McKenna: My next question is: You're licensed by Health Canada. When was your last inspection?

Ms. Marita Zaffiro: I'm licensed by Health Canada? I don't believe I said that in my statement.

Mrs. Jane McKenna: Oh, okay. Sorry, I apologize.

Ms. Marita Zaffiro: It's only recently that Health Canada has laid out the provisions for this kind of activity, and one of them is under the supervision of a licensed pharmacist.

Mrs. Jane McKenna: Okay. Did—okay, go ahead.

The Chair (Mr. Ernie Hardeman): Mr. Yurek.

Mr. Jeff Yurek: Thanks for coming in today. It's good to see you. Can you give us an overview of your accreditations in your pharmacy?

Ms. Marita Zaffiro: In our Hamilton location that previously provided service to most of HNHB CCAC for home intravenous therapy—during the years that we have been providing services to part of that region and then all of that region, we became one of the first pharmacies in Canada and the first in Ontario to be ISO-registered. Further, over time we then adopted the accreditation standards and were accredited by the Canadian Council on Health Services Accreditation, now known as Accreditation Canada. That's the body that accredits hospitals, long-term-care facilities and now many community organizations.

Those are our two accreditations. We're now in the process of actually accrediting our Kitchener location under ISO.

Mr. Jeff Yurek: And that clearly has a lot to do with quality?

Ms. Marita Zaffiro: It does indeed. Way back then, our desire was to be accredited by the American standard on home care infusion therapy, which was called JCAHO, but they unfortunately declined to come and accredit in Canada, and there was no similar standard. After much consideration and analysis, we decided to go to ISO because Accreditation Canada also wouldn't accredit community pharmacy activities around sterile products preparation.

Mr. Jeff Yurek: And were there clear guidelines on what Medbuy expected from you in compounding the product? You stated earlier that maybe it was a little

muddled—or was it clear, "This is the product we want"? Because you're saying—

Ms. Marita Zaffiro: No, I don't think it was muddled.

Mr. Jeff Yurek: No? It was fairly clear what they expected—

Ms. Marita Zaffiro: There was a lot of opportunity for discussion, and we have a lot of documentation going through these products.

Mr. Jeff Yurek: If you were offered, in the contract negotiations, to provide quality testing, batch testing, would you have complied with that?

Ms. Marita Zaffiro: We don't make any batch product. We make every product to order. Much like a community pharmacy would a prescription, if the order is our prescription, we do not combine orders across hospitals. We do not pre-make any product. So if a hospital wants 50 bags, we make that, and that's it. We make to order. The end-product testing is done on a periodic basis, but the need to do it in the same way as if you were batching and keeping stock on a shelf or had prolonged expiries is not as critical. So you're asking if I'd be willing to it? We do do some, and that's something that we could do more as our volumes or our demands increase.

Mr. Jeff Yurek: And have you ever heard any problems from your hospital regarding your labelling? Did they ever call you up? But I imagine they'd call Medbuy. Did Medbuy ever say—

Ms. Marita Zaffiro: No. They would probably call us, actually. That's pretty much how this started, with a call to our pharmacist on site from Peterborough to say, "Hey, the label says this, and there's more in the bag," so trying to understand, and she had identified that inconsistency with how they were using it and how it was labelled and prepared. They were a new purchasing hospital so this was their first dose that they were using, and they immediately identified that, "Oh, this is not right," and so they called us immediately, and that was how this issue began to be unravelled and discussed and understood.

Mr. Jeff Yurek: But the other hospitals never called to question—

Ms. Marita Zaffiro: No, it was never identified to us by any of the other hospitals.

Mr. Jeff Yurek: Would we be able to get a copy of the contract, the wording of it and stuff? Is that possible?

Ms. Marita Zaffiro: Yes.

Mr. Jeff Yurek: Thank you, Chair.

The Chair (Mr. Ernie Hardeman): Ms. Elliott.

Mrs. Christine Elliott: A few quick questions. Thank you very much, Ms. Zaffiro, for coming before the committee today.

You mentioned earlier that you had gone both to the College of Pharmacists and to Health Canada, and they declined to regulate. Can you describe that process and whether there's any correspondence that we could obtain that would confirm that?

Ms. Marita Zaffiro: There is some correspondence. There are also several conversations that are logged and

discussed. Basically, there was not a place—there was a gap—for what we were doing that wasn't covered in one regulation or the other. We informed that we were moving forward. We confirmed what our processes were, that a pharmacist would be overseeing that operation, and our hope was that—and the way we left it—we wanted to be regulated. So we were aware that Health Canada and OCP and perhaps other provinces were working on this, and we were monitoring and hoping to hear that there was soon to be the opportunity for us to be regulated.

Mrs. Christine Elliott: But it was very clear that both Health Canada and the College of Pharmacists were aware of this gap or grey area some time ago?

Ms. Marita Zaffiro: Yes. You understand that this gap has existed for a long time, and several practitioners provide service in this gap.

Mrs. Christine Elliott: Would you undertake to provide us with copies of that correspondence?

Ms. Marita Zaffiro: Yes, I can. I will.

Mrs. Christine Elliott: Thank you. My other questions just really relate to the issue with respect to hospitals seemingly not knowing that it was a non-concentrated solution that they were being provided with. In your opinion, should a pharmacist in a hospital have been able to tell that from looking at the labelling on the bag? Should there have been this confusion?

Ms. Marita Zaffiro: Should they be able to tell from the labelling?

Mrs. Christine Elliott: Yes.

Ms. Marita Zaffiro: All I can say is that the products we provided were not concentration-specific, they were not labelled as concentration-specific, and to use them otherwise would have been incorrect.

Mrs. Christine Elliott: So any reasonable pharmacist knowing how to practise would have been able to tell from the labelling on the bag that it was a non-concentration-specific product?

Ms. Marita Zaffiro: I think that there are a lot of recognized issues with labelling and interpretation and assumption. ISMP has identified that there is a need for a national labelling standard. The interfaces of communication, whether they're Marchese and Medbuy, Medbuy and the hospital, the hospital pharmacy and the floor, or the floor and the administrator: There are a lot of opportunities for that communication not to be as clear as it could be.

Mrs. Christine Elliott: In your discussions with Medbuy that led to your being awarded the contract, was there any discussion about who would be the provider of concentration-specific solutions? If you were to provide the non-concentration-specific one, who else would be providing the solutions that would have been the concentration-specific ones?

Ms. Marita Zaffiro: We would have provided it if we understood they wanted it. So, again, if there had been clarity there, if they had asked us, then I assume that we would have been the provider as well.

Mrs. Christine Elliott: But there was no discussion that you had with respect to the other type of solution and who was going to be providing it?

Ms. Marita Zaffiro: No, none at all. No.

Mrs. Christine Elliott: Thank you. Those are all the questions for now.

The Chair (Mr. Ernie Hardeman): The third party: Ms. Gélinas.

M^{me} France Gélinas: Thank you.

Some general questions: First, can you give me an idea of the size of your company? I'm looking at how many people work for you. Are they professional? If they are, what kind of credentials do they hold? Give me an idea of the size.

Ms. Marita Zaffiro: The group of companies employ 80 people across all those operations and locations. There are 15 pharmacists, several pharmacy technicians who are registered; many pharmacy assistants, customer service people, warehouse technicians etc.; and then administrative people and corporate services people.

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M^{me} France Gélinas: Okay. More specifically in MHS, how many people work in that division?

Ms. Marita Zaffiro: About 20.

M^{me} France Gélinas: And of the 20 who work there, how many pharmacists, how many pharmacy technicians, how many pharmacy assistants?

Ms. Marita Zaffiro: There are two pharmacists, one registered pharmacy technician, several infusion technicians and several warehouse technicians.

M^{me} France Gélinas: You'll have to forgive me; I don't know. What does a warehouse technician do in a pharmacy?

Ms. Marita Zaffiro: Just the logistics of preparing the order to be delivered—to be shipped to the hospital—and the packaging.

M^{me} France Gélinas: Okay. So two pharmacists, one regulated technician—I'm at 17. The infusion and warehouse: What's the breakdown between the two?

Ms. Marita Zaffiro: I don't have the exact numbers, to tell you the truth.

M^{me} France Gélinas: But the other 17—

Ms. Marita Zaffiro: The majority of the staff are infusion technicians. That's who produces the admixtures. So there might be at least 10 of them.

M^{me} France Gélinas: Okay. And the balance would work in—

Ms. Marita Zaffiro: Administration or customer service or the warehouse.

M^{me} France Gélinas: Where do you get your infusion therapists?

Ms. Marita Zaffiro: Technicians?

M^{me} France Gélinas: Technicians—sorry.

Ms. Marita Zaffiro: That's okay. Where do we get them? We recruit them. Many have been trained at our other operations, or we advertise for them, and they are usually college trained and then electively become registered technicians with the College of Pharmacists.

M^{me} France Gélinas: Okay. It's an elective, so they would be allowed to practise whether they are under the College of Pharmacists or not?

Ms. Marita Zaffiro: That's correct. They can be college-trained pharmacy technicians, but they're not necessarily registered technicians unless they get licensed with the Ontario College of Pharmacists.

M^{me} France Gélinas: Okay, sounds good. And could some of them not be college trained?

Ms. Marita Zaffiro: All of our technicians are college trained. Some are historically—they were certified pharmacy technicians. That's no longer a designation. Technicians are now licensed, and they have some additional scope of duty.

M^{me} France Gélinas: Okay. Coming back to some of what my colleague was talking about: You had this opportunity to bid on this new contract, you feel that you're able to deliver, you decide on a different corporate structure to handle this new work, but you were already preparing IV for your home care side. Why the need for the new corporate structure?

Ms. Marita Zaffiro: Marchese Hospital Solutions would have been regulated if it could have been regulated. But it would have been a new company, and it would have been Marchese Hospital Solutions. The reason for a new structure is that it's prudent. But besides that, this is a new business, a new location and a new type of customer. So the desire was to be able to focus on that unique element of our new business unit and to structure it that way.

M^{me} France Gélinas: Okay, but still under the overall corporation of Marchese?

Ms. Marita Zaffiro: It has the same brand name.

M^{me} France Gélinas: Okay.

Ms. Marita Zaffiro: These are separate corporations, and one does not flow into the other.

M^{me} France Gélinas: Okay, I get it.

When you entered into talks with—let's take them one at a time—Health Canada, which declined to regulate you, what was their reason for not doing so?

Ms. Marita Zaffiro: They were of the opinion that we could do what we were doing as a regulated pharmacy.

M^{me} France Gélinas: Okay, and you accepted that it was not in the purview of Health Canada to do this, and then you went to the College of Pharmacists. What happened?

Ms. Marita Zaffiro: They do not regulate the activity that Marchese Hospital Solutions was doing for hospitals.

M^{me} France Gélinas: So they were aware that you were doing those activities. Had you told the college that Health Canada had more or less refused to regulate you?

Ms. Marita Zaffiro: My understanding was that Health Canada and the college were in discussions around looking at this gap and how it was going to be addressed.

M^{me} France Gélinas: Did the Ministry of Health have any way of finding that out?

Ms. Marita Zaffiro: I don't know how.

M^{me} France Gélinas: Okay. You mentioned that there are other corporations that work similarly—you didn't use the word "corporation," but other people working in that grey area.

Ms. Marita Zaffiro: Service providers?

M^{me} France Gélinas: Service providers—good word. Could you name me some other service providers?

Ms. Marita Zaffiro: Yes, I think I did in the record. So—

M^{me} France Gélinas: Oh, sorry, it's been done? It happens.

Ms. Marita Zaffiro: I know.

M^{me} France Gélinas: So there are others that practise in Ontario and that are in the same—what has been called so far—"grey area."

Ms. Marita Zaffiro: We were aware that there was one; there was one provider and only one provider, long-standing—two hospitals for this service.

M^{me} France Gélinas: You started out this new corporation, you tried to get regulation, and you ended up putting in the best practices you could think of.

Ms. Marita Zaffiro: Correct.

M^{me} France Gélinas: When they talked about what you were preparing for them, they talked about bulk. Why would they use this if it was—

Ms. Marita Zaffiro: Who talked about bulk? I'm sorry?

M^{me} France Gélinas: The people who were there before you, when London said that you were preparing the drug as a bulk purchase.

Ms. Marita Zaffiro: No, I believe they were using the product as a bulk product. Please understand that what we have learned now is that hospitals were using our products in a way that we had no idea of. We did not know that they were using these for multi-patient use. It was not specified or discussed at any time during the year-plus of the contract being serviced.

M^{me} France Gélinas: I understand that they were 200-ml bags that you were delivering to the hospitals?

Ms. Marita Zaffiro: Yes, 200 ml plus the overfill.

M^{me} France Gélinas: Plus the overfill. So, in everybody's mind, a dose would have been four grams in 200 ml. Everybody who prepares it in your pharmacy thought that that was going to be for one single patient?

Ms. Marita Zaffiro: We prepare what Medbuy asks us to prepare. We do not evaluate what they ask for in the bag. We put the precise amount of drug in the bag that they request.

M^{me} France Gélinas: When you were dealing with Medbuy to get this contract—actually, we were told that Medbuy was just going to renew the contract with Baxter, and it was when you saw it posted that you asked that you be considered?

Ms. Marita Zaffiro: The way the process works—I'm sure you're all aware that there are procurement laws for public institutions in Ontario over \$100,000. So Medbuy posted a notification that, to the best of their knowledge, there was only one provider of these services, and they intended to procure those services from that monopoly provider unless they heard otherwise.

Given that we had the experience and the facilities to demonstrate our capabilities and the desire to do what needed to be done to provide this service, we declared

that we thought we could provide the service if they were looking for an additional provider in their market in two hospitals in Ontario. So they came and visited our site in Kitchener and they seemed to be quite pleased that, indeed, we did have the ability to provide these services. They saw our facilities, our staff working, our systems etc.

So when they left, they said they were going to RFP. So it took some time, but that RFP began or was supposed to have begun, I believe, in February 2011. It didn't conclude till the middle of December 2011, and we provided service beginning the middle of February.

M^{me} France Gélinas: Okay. Who were you with at Medbuy?

Ms. Marita Zaffiro: Who was I dealing with at Medbuy? Actually, it was my staff who dealt with Medbuy directly; I did not. So if you need that information, we can make that available.

M^{me} France Gélinas: Yes, please, if you could table that with the Clerk, the people you that were dealing with. And who within Marchese—which one of your staff handled that—

Ms. Marita Zaffiro: Pharmacists were dealing with pharmacists between Marchese and Medbuy. So again, there was an expectation that pharmacists throughout that chain understand their responsibility in that piece of the process.

M^{me} France Gélinas: So from Marchese you had put a pharmacist or a licensed pharmacist in charge of this and he or she—who was it, anyway? I'll make it easier.

Ms. Marita Zaffiro: It's a she—shes.

M^{me} France Gélinas: She? What's her name?

Ms. Marita Zaffiro: It's shes—it's been several pharmacists that have had that relationship over time.

M^{me} France Gélinas: The initial?

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Ms. Marita Zaffiro: The initial one was—actually, we had a team of pharmacists who would be working on this. Do you want people's names?

M^{me} France Gélinas: Yes.

Ms. Marita Zaffiro: Janie Bowles-Jordan, Laura Savatteri—

M^{me} France Gélinas: You went too fast. Try again.

Ms. Marita Zaffiro: Can I give them to you—

M^{me} France Gélinas: Yes, you can.

Ms. Marita Zaffiro: I want to make sure I give you the right names and all the names, because it was a period of time in terms of that process.

M^{me} France Gélinas: And you know for a fact that the people they were dealing with at Medbuy were also pharmacists?

Ms. Marita Zaffiro: Yes.

M^{me} France Gélinas: Did any of them have experience dealing with oncology drugs before?

Ms. Marita Zaffiro: My staff?

M^{me} France Gélinas: Yes.

Ms. Marita Zaffiro: In the home care environment we had made several oncology drugs, but mostly 5-fluorouracil. Most of the oncology drugs in the home

care environment were actually made by the cancer centres themselves and so were not administered in home care settings.

M^{me} France Gélinas: Okay. And for home care, it would all be an individual bag for an individual?

Ms. Marita Zaffiro: Correct.

M^{me} France Gélinas: So they never needed—

Ms. Marita Zaffiro: Which is what admixtures usually are. When we talk about an admixture, an admixture means a dose for a patient. If someplace it says we're making bulk stock solutions, then we understand that to be something different.

Now, you could use a non-concentration-specific product, but it would be very complicated and it wouldn't be worth the manipulation to actually use it for a multi-dose purpose.

Ms. Cindy Forster: I just want to follow up on Ms. Gélinas's question regarding the specific dosage. You were under the impression that these were going to be one dose, one patient. I don't think that we've heard from any of the hospitals at this point as to what a normal dosage of either of these two drugs would be, but I'm assuming that the dosage that was in the bags that you actually prepared is significantly greater than one patient would be administered at any one time, and I wouldn't expect that a minibag would be administered partially and then used again on a subsequent day for chemotherapy. So my question is, was there more than a one-patient dose, based on an average-size body mass, in that bag, and would it be reasonable to expect that pharmacists would pick up on that at your facility if your assumption was that this one bag with this dosage of drug was going to one patient for one treatment?

Ms. Marita Zaffiro: Our responsibility in providing the service to hospitals is to ensure that we combine the products that they ask for in a sterile environment with very high quality-control standards. Our role is not to evaluate what the hospital asks us to make in terms of the clinical appropriateness of what they put in the bag. We are not physicians, we are not working directly with patients. We have that limited role, and we did not see that as our responsibility in this service process.

Ms. Cindy Forster: Do you have any comment, though, with respect to the dosage of the drug that was actually in a bag that you assumed—

Ms. Marita Zaffiro: We certainly have come to understand that the dosage could be—there was four grams in the bag. The dosage could be possibly anywhere from 500 milligrams to 2,000 milligrams per person. But you know what? I'm not an expert in oncology.

Ms. Cindy Forster: Okay. Thank you.

M^{me} France Gélinas: So you put in some effort to try to get oversight, to try to get accredited either by the college or by the federal government. Had the Ministry of Health asked you to comply with regulation, any doubts that you wouldn't have followed?

Ms. Marita Zaffiro: No, of course not. In fact, we have submitted thousands of pages of documents, and my understanding is that Health Canada has indicated that

we have appropriate measures in place. So the lack of regulation or regulations would not necessarily have prevented this incident.

M^{me} France Gélinas: You really focus on communication. You prepared the drugs the way they wanted them to be labelled and prepared—

Ms. Marita Zaffiro: That is correct.

M^{me} France Gélinas: —and they used them in a way that was not labelled or prepared.

Ms. Marita Zaffiro: We had no way of knowing how they're using them. What is becoming apparent is that different hospitals use them in different ways. Reading some of the testimony, it sounds like some hospitals think the labels are okay and accurate and some think that they're wrong. So, again, if there is that degree of inconsistency amongst the hospitals, then you can appreciate that we needed to make a consistent, high-quality, sterile product. Hospitals are responsible for understanding what they're receiving, how they use it, how they administer it and the patients who need it.

M^{me} France Gélinas: We'll save our time.

The Chair (Mr. Ernie Hardeman): You have about three minutes left.

M^{me} France Gélinas: I'll use them wisely.

The Chair (Mr. Ernie Hardeman): Okay. Thank you. Yes, Ms. Damerla?

Ms. Dipika Damerla: Thank you, Chair.

As you know, the government is proposing some new regulations. Can you tell us how that would impact your business?

Ms. Marita Zaffiro: It will be positive in terms of having clear expectations and standards around regulation, but I believe that it will not require a lot of changes in the way we operate, our processes or our systems. I'm fully open to working with the college and Health Canada to help inform those standards and expectations and utilize our expertise and our systems to make that more easy to happen.

Ms. Dipika Damerla: You said that your process wouldn't change much because of the proposed regulations. What would change, though?

Ms. Marita Zaffiro: I think just the clarity of the fact that this kind of service can be conducted under the supervision of a licensed pharmacist. Whether that will be a pharmacy or not, I don't know. They're releasing some potential changes to the regulations for comment. I have not had a chance to review them. So I don't know; it will depend on what they come up with.

Ms. Dipika Damerla: Has the college or Health Canada visited your facility since this issue came to light?

Ms. Marita Zaffiro: Yes, they jointly visited our facility and were given access to both the regulated and non-regulated portion of the facility.

Ms. Dipika Damerla: Can you further describe your communication with the college or Health Canada or Dr. Thiessen?

Ms. Marita Zaffiro: We met with Dr. Thiessen. He met with me and some of my staff. We've been in communication with both Health Canada and the college,

several letters—Health Canada, OCP and the Ministry of Health have been working together, and so jointly they requested and, I believe, reviewed documentation that we provided and questions that we answered, along with their site visit, to satisfy themselves that we have appropriate measures in place.

Ms. Dipika Damerla: I'd like to revisit the issue of—you created a new entity which was Marchese Hospital Solutions. You created this after winning the contract. Were you aware that by creating this, you would lose oversight?

Ms. Marita Zaffiro: Yes, but you have to understand, we wanted—actually created it, and we wanted it to be accredited. So we were working, at the same time—this was a very short period of time—to actually get it accredited and get it started up. So Marchese Hospital Solutions ideally would have been an accredited pharmacy or accredited by Health Canada.

Ms. Dipika Damerla: Right. Okay; thank you. I'll turn it over to my colleagues.

Mr. Lorenzo Berardinetti: We're fine.

The Chair (Mr. Ernie Hardeman): Thank you. You have one minute left.

Mr. Lorenzo Berardinetti: Okay. We'll save it.

The Chair (Mr. Ernie Hardeman): Thank you, Mr. Berardinetti. Ms. Elliott?

Mrs. Christine Elliott: Thank you. You've indicated that you've had communications with both Health Canada and with the College of Pharmacists. Have you had any communication, either before or after this problem surfaced, with either the Ministry of Health or with Cancer Care Ontario?

Ms. Marita Zaffiro: The Ministry of Health was involved in arranging the conversation I had with Dr. Thiessen, so there was a phone call there. This was subsequent, of course, to the incident. I have had no communication whatsoever at any time from Cancer Care Ontario.

Mrs. Christine Elliott: And the ministry was aware that you were setting up this new business, I'm assuming, or—

Ms. Marita Zaffiro: How would the ministry know? I'm sorry; I don't know how that—

Mrs. Christine Elliott: But you've never been contacted by anyone until you were approached to have the conversation with Dr. Thiessen?

Ms. Marita Zaffiro: No. When we were contacted through Health Canada, it was clearly stated that their inquiry of Marchese Hospital Solutions and the information they were requesting was done for the purposes of Health Canada, OCP and the Ministry of Health and Long-Term Care to use to understand what we were doing, how we were doing it and what controls we had in place. So the ministry—I mean, it was not a personal contact, but it was through that process that—

Mrs. Christine Elliott: So presumably the Ministry of Health was brought into the loop that there was an issue.

Ms. Marita Zaffiro: I couldn't speculate. I don't know; I'm sorry.

Mrs. Christine Elliott: But they never contacted you directly, and you've not had any contact with them until recently.

Ms. Marita Zaffiro: No, I don't think so.

Mrs. Christine Elliott: Okay. Thank you.

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The Chair (Mr. Ernie Hardeman): Ms. Gélinas?

M^{me} France Gélinas: Just to check: Medbuy approved of your labelling, and you complied with whatever labelling Medbuy had asked you to submit?

Ms. Marita Zaffiro: Yes.

M^{me} France Gélinas: Okay. How big a contract was that for you? Just give me a size.

Ms. Marita Zaffiro: Financially?

M^{me} France Gélinas: Yes.

Ms. Marita Zaffiro: Well, I know that we've produced about 460,000 units of infusion bags in the life of the contract, so let me just do some math.

M^{me} France Gélinas: Keep me in the loop there. That's 460 times—

Ms. Marita Zaffiro: I really am estimating; I'm sorry: about \$2 million.

M^{me} France Gélinas: About \$2 million, and when you first got the contract—there was a competitive process. When you first got the contract, do you figure—you provided economies of scale, you provided economic benefits to the hospital. Had you been way more expensive than hospital staff mixing those drugs, do you figure you would have gotten the contract?

Ms. Marita Zaffiro: I don't think that's the primary reason to outsource admixture production. As you heard, or if you see our facility, it is a large facility. It is built to the standards of 797—a very significant investment to do that. Most hospitals would not be able to do that, nor does it make sense for every hospital to have a 797-level facility. It makes sense in terms that if hospitals aren't, say, making chemo on a regular basis, then their staff can't really maintain their competency if they're not doing it all the time. The opportunity to centralize a repeatable operation, maintain staff competency and ensure a higher level of quality and a higher level of safety, along with economies of scale—that ideally would give

you some opportunity to keep more of the health care drug budget in the hospital's hands and direct it to patient care.

M^{me} France Gélinas: So what do you figure in your proposal—they selected you; they could have gone to two different ones. Do you have a feeling as to how come you were successful when the other two were not?

Ms. Marita Zaffiro: What we were told, as I said earlier, is that our labelling, at their request, was able to utilize two or three important safety elements. One was ISMP-recommended, but not required, tall man lettering, and colour coding and alert labelling. They found that this was clear. This was something they wanted. I assume this was something that was not available to them previously.

In terms of price, I have no idea. However, I know that the way we provide this service is a bit of a unique business model, so what they had requested and what we were doing was a little different. We provide the service, and our revenue comes from the service of compounding the admixture. The cost of the medication is a flow-through and is not marked up. That means there is likely a positive financial benefit to the hospitals that use this service over the existing or pre-existing arrangement. However, I am not privy to the exact details of the pre-existing arrangement.

The Chair (Mr. Ernie Hardeman): I'm glad you've used it wisely, because it's all gone. Thank you very much.

The government side, you have one minute left.

Mr. Lorenzo Berardinetti: We're fine, thank you.

The Chair (Mr. Ernie Hardeman): Okay. Thank you. The opposition, do you have any further questions?

Mrs. Christine Elliott: We're fine. No further questions.

The Chair (Mr. Ernie Hardeman): No further questions? Then that concludes the events today. Thank you very much for making your presentation, and we look forward to further deliberation on this issue.

With that, the committee stands adjourned until 4 o'clock tomorrow afternoon.

The committee adjourned at 1734.

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Tuesday 30 April 2013

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Mardi 30 avril 2013

Standing Committee on Social Policy

Oversight of pharmaceutical
companies

Comité permanent de la politique sociale

La surveillance, le contrôle et la
réglementation des entreprises
pharmaceutiques



Chair: Ernie Hardeman
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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Tuesday 30 April 2013

Mardi 30 avril 2013

*The committee met at 1600 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIESPETERBOROUGH REGIONAL
HEALTH CENTRE

The Chair (Mr. Ernie Hardeman): I call the meeting of the Standing Committee on Social Policy to order. We are here to do a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

Our presentation today will come from the Peterborough Regional Health Centre. In fact, they were here before I got here, and I got here quite a bit earlier. I'm glad to see we're here and already all seated there.

We will be doing the hearing under oath, so the Clerk will ask each one of you to either affirm or swear the oath, and then we will start the process.

The Clerk of the Committee (Mr. William Short): We'll go left to right. Mr. McLaughlin, did you want to swear the oath or be affirmed?

Dr. Peter McLaughlin: I will be affirmed.

The Clerk of the Committee (Mr. William Short): Okay. If you could just raise your right hand, please.

Mr. McLaughlin, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Dr. Peter McLaughlin: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Ms. Freeman?

Ms. Laura Freeman: I'll swear an oath.

The Clerk of the Committee (Mr. William Short): Okay. The Bible is in front of you there. Thank you.

Ms. Freeman, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Laura Freeman: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Mr. Tremblay, did you want to do the oath as well?

Mr. Ken Tremblay: I'll affirm.

The Clerk of the Committee (Mr. William Short): You'll affirm. Thank you.

Mr. Tremblay, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Ken Tremblay: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much again for being here. We will have 20 minutes for you to make your presentation, and you can use that in any way. All three can speak or one can speak. At the end of your presentation, we will then have questions. We'll start with the official opposition, and each party will have 20 minutes to ask any questions on your presentation and any question relating to the issue at hand.

With that, the floor is yours.

Mr. Ken Tremblay: Thank you very much, Mr. Chair, ladies and gentlemen of the committee. On behalf of the board, the leadership team, and staff and physicians, thank you very much for the opportunity to provide this committee with information around the recent chemotherapy drug incident.

I'd like to begin by introducing myself and colleagues from the Peterborough Regional Health Centre.

My name is Ken Tremblay. I took over as president and CEO of PRHC in 2010. Since receiving my master's in the good old days of 1980, I've had the privilege of being the president and CEO of St. Joseph's Hospital in Brantford; York Central Hospital, now Mackenzie Health, in Richmond Hill; St. Boniface Hospital, a teaching hospital in Winnipeg; recently the Chatham-Kent Health Alliance; and now Peterborough.

Sitting to my right is Laura Freeman, vice-president responsible for clinical services, including cancer care. She joined PRHC in December 2010 from the Royal Victoria hospital in Barrie. She has held senior positions at the Northeastern Ontario Regional Cancer Centre and has completed an advanced health leadership program at the Rotman School of Management, University of Toronto.

Dr. Peter McLaughlin is our chief medical officer, chair of our medical advisory committee and vice-president responsible for clinical and support areas, including pharmacy. Dr. McLaughlin was formerly a professor of medicine, University of Toronto, and a staff cardiologist at the University Health Network. He remains an adjunct clinical professor of medicine at the U of T. He is a fellow of the Royal College of Physicians

and Surgeons of Canada and the American College of Cardiology. He undertook postgraduate training at the Ottawa Civic Hospital, Toronto General Hospital and Stanford University Medical Center in California.

Brenda Weir is the director of emergency, lab, diagnostic imaging and pharmacy at the Peterborough Regional Health Centre. She is a registered nurse by training, with 24 years of hospital leadership experience.

Margot DaCosta is director of renal, metabolic and cancer care programs at PRHC. She is a registered nurse with 25 years' experience.

Also joining us is Arnel Schiratti, who is director of strategic communications and engagement. His public sector career spans some 12 years in the Ministries of Health and Energy, Science and Technology, with nearly 10 years of hospital communications and engagement experience.

Laura, Peter and I appreciate the opportunity to make brief opening statements.

I wish to begin by recognizing that the committee has already heard from a number of provincial organizations and hospitals prior to our appearance. We will attempt to avoid unnecessary duplication for the committee.

To give you some specs about the organization, we're a regional health centre, about 400 beds, providing regional and locally focused health services to up to 600,000 residents. We have some 2,000 staff, 350 physicians and 600 volunteers on staff who are focused on providing high-quality, safe care in such areas as emergency, surgery, general medicine and regional services. Regional services include dialysis, stroke, mental health, diabetes, cancer care, vascular surgery and cardiac care.

More specifically, with respect to our role in cancer care and our cancer care clinic, it has grown by some 85% in the last five years. Each year, our organization performs about 640 cancer surgeries; 20,700 chemotherapy treatments for nearly 6,700 patients; screening services, like colonoscopies—about 500 of those; 2,600 colposcopy screens; and 7,800 breast-screening visits. Soon, in the next few months, we'll be opening our new radiation cancer suite, bringing additional cancer care closer to home for some 300 patients annually.

Our current and expanding cancer role would not have been possible without the support of Cancer Care Ontario and the Central East Regional Cancer Program, based at the R. S. McLaughlin Durham Regional Cancer Centre in Oshawa. I understand they were before you on April 23. Through the support of their cancer physicians, medical oncologists and radiation oncologists, and other clinicians and specialized clinical support personnel, we are able to serve cancer patients closer to home.

Our relationship, along with individual and mutual accountabilities, is guided by a memorandum of understanding between ourselves and the respective centres. In practical terms, through the Durham Regional Cancer Centre, cancer specialists and pharmacists come to Peterborough to care for patients and provide medical oversight to our nurses and clinical support staff, such as pharmacy assistants.

More specifically, as it relates to chemotherapy at PRHC, medical oncologists—physicians—from the DRCC assess patients, determine their course of treatment and oversee patient care at PRHC.

PRHC's nurses administer treatments ordered by these specialist physicians. Pharmacy assistants and technicians employed by the organization gather and, in some cases, prepare drug regimens under the guidance and direction of pharmacists from the Durham Regional Cancer Centre. The Durham Regional Cancer Centre supplies these drugs to PRHC through its various supply contracts.

Now it's my pleasure to pass this on to Laura, who will make her comments.

Ms. Laura Freeman: Thank you, Ken, and good afternoon, members of the legislative committee. As vice-president responsible for clinical services such as cancer care at the Peterborough Regional Health Centre, I wish to focus on the chronology of events in the identification and reporting of the incident and the steps staff and officials of PRHC took to contain the impact on our patients and notify the supplier and Durham Regional Cancer Centre.

You have heard from Cancer Care Ontario, the Ministry of Health and Long-Term Care, the Ontario College of Pharmacists and other impacted hospitals. Therefore, in the interest of time, I will attempt to limit the review of events to those that occurred at PRHC prior to April 2, 2013.

Peterborough Regional Health Centre's supply of chemotherapy drugs is through our relationship with the Durham Regional Cancer Centre. We receive our drugs under their contract.

On March 20, 2013, the supply of gemcitabine from the previous supplier, Baxter, had been depleted and the new supply of gemcitabine from the new supplier, Marchese, was used for the first time that afternoon at 2:20 p.m. At that time, the pharmacy assistant noticed that the label on the Marchese product differed from the labelling on the Baxter product. The Baxter and Marchese product labelling were compared, since the Baxter bag was still available.

The Marchese label indicated: gemcitabine, four grams in 100 millilitres only. The Baxter label indicated: 4,000 milligrams; total volume, 105.26 millilitres; gemcitabine, 38 milligrams per millilitre.

The pharmacy assistant noted that the Marchese label indicated 4 grams in 100 millilitres and began to question if that was the total volume and what the final concentration per millilitre was.

The pharmacy assistant also noted that the electronic preparation worksheet used to calculate the dose used 38 milligrams per millilitre, which had been the Baxter final concentration of four grams in 105.26 millilitres. The pharmacy assistant questioned whether the final concentration was 40 milligrams per millilitre.

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The on-site Durham Regional Cancer Centre pharmacist was called and consulted regarding the bag labelling

and the concentration, and if the electronic worksheet had been corrected for concentration of the gemcitabine Marchese bag. The Durham Regional Cancer Centre pharmacist instructed the PRHC pharmacy assistant to hold the treatment until hearing back from them.

The DRCC pharmacist consulted a second DRCC pharmacist, questioning the worksheet concentration for the gemcitabine Marchese bag. The PRHC pharmacy assistant consulted the PRHC senior pharmacy assistant regarding the concentration of the Marchese bag. The senior pharmacy assistant noted that the Marchese product was mixed in a Hospira bag, which has a known overfill of seven millilitres. It was not clear from the labelling on the Marchese bag if the overfill had been included in the determination of the final concentration.

Marchese was called and the senior pharmacy assistant asked about the concentration. When asked about the overfill changing the concentration, Marchese staff indicated that it was still four grams in 100 millilitres. They asked if the pharmacy assistant would like to speak to a Marchese pharmacist, and we agreed.

The PRHC manager of cancer care was made aware by the pharmacy assistant that there was a potential issue with the gemcitabine and they were working to find out further information.

A Marchese pharmacist contacted the PRHC pharmacy assistants and they advised that the final concentration would not change because the entire contents would be administered to the patient. The pharmacy assistants explained the process for the dose delivery: that the patient would not receive the entire contents of the bag and that the entire four grams would therefore not be given to a patient. The Marchese pharmacist stated they would need to investigate further.

At 4:05, the on-site DRCC pharmacist received a call from another DRCC pharmacist and was instructed not to use either the Marchese gemcitabine or cyclophosphamide prepared products.

At 4:10, the on-site DRCC pharmacist emailed the PRHC cancer care pharmacy team that the supply of the gemcitabine and cyclophosphamide product from Marchese were not to be used until further clarification about the exact concentration of the drug in the bags could be confirmed. PRHC discontinued immediately the use, and the supply of gemcitabine was quarantined in the PRHC pharmacy.

At 4:58 p.m., the senior pharmacy assistant received an email from Marchese indicating that they were working on a solution and would provide follow-up.

On Friday, March 22, at 1:34 p.m., PRHC manager of cancer care received a call from Dr. Leta Forbes, chief medical oncology at the DRCC, confirming an issue with respect to the concentration of gemcitabine and cyclophosphamide supplied by Marchese. She confirmed that PRHC had one patient who had received the Marchese gemcitabine in question as part of their treatment.

Late that day, I was informed in person by Tom McHugh, regional vice-president, cancer, at DRCC that

Peterborough had one patient affected and that DRCC had ongoing investigations.

We followed the coordinated process and timelines for informing patients affected and communications established by DRCC.

The medical oncologist met with the PRHC affected patient on April 2, 2013.

PRHC ensured all cancer care staff were informed and able to answer questions and concerns raised by patients coming to the hospital for care, as well as those calling to make inquiries.

Margot DaCosta, the director of renal, metabolic and cancer services, is also here to assist us with responding to the committee's questions.

And now, Dr. Peter McLaughlin would like to make a final address.

Dr. Peter McLaughlin: Thank you, Laura

Mr. Chair, ladies and gentlemen, as Ken said, I am the chief medical officer for PRHC and have additional duties for quality, risk and safety as chair of the medical advisory committee, and VP for the emergency department, quality, risk and clinical support services like labs, diagnostic imaging and pharmacy.

I also wish to recognize my colleague Brenda Weir, our director of emergency, labs, DI and pharmacy.

In light of the innovative relationship between PRHC and the Durham Regional Cancer Centre, I wanted to take a few moments to briefly outline for the committee the interprofessional, inter-organizational and, in practical terms, the professional responsibilities of the many health professionals involved in the care of our cancer patients.

Patients are generally referred to our cancer program through their family physician or primary care provider. Following a series of tests and upon determination of a cancer diagnosis, a treatment plan is ordered by the appropriate specialist. In the case of chemotherapy treatment, this physician is a medical oncologist from the Durham Regional Cancer Centre who is jointly appointed to Durham Regional Cancer Centre and PRHC. These specialists see patients in both Oshawa and Peterborough.

As determined by the patient's needs, the medical oncologist may prescribe a chemotherapy drug regimen. This order is reviewed by the DRCC's pharmacists and, in turn, prepared by one of PRHC's pharmacy assistants for administration to the patient by a nurse employed by our hospital.

Each health professional has clearly defined duties and obligations within their scope of practice. They are encouraged and empowered to raise issues or concerns with respect to safety and quality with the appropriate health professional.

For example, a pharmacy assistant is to raise questions with the pharmacist who is responsible for directing and supervising the pharmacy assistant. Should a pharmacist have concerns, these would be raised with the prescribing physician.

As Laura identified through her earlier description of events, several pharmacy assistants were involved in

raising questions and escalating the issue internally with the DRCC pharmacist and supplier.

Peterborough Regional Health Centre is very proud of these alert and dedicated staff and all of our health professionals who are continually focused on safe, excellent quality care. We recently recognized these three staff members at a private ceremony at Peterborough Regional for doing what we call "a good catch."

I wish to reassure the committee that, as with all of our officials and staff at PRHC, they spoke openly, honestly and fully with Dr. Thiessen in his interviews. The hospital has been inundated with persistent and determined requests to recognize their contribution.

We have honoured their desire to remain private, as they have asked, allowing them the ability to focus on the important task of continuing to do their part in helping patients in their personal battles against cancer.

Finally, I would like to underline that PRHC supports the process set out by the independent expert panel under the leadership of Dr. Thiessen.

Also, it is important to acknowledge that objective assessments of incidents such as these in many industries normally point to multiple, successive failures in seemingly independent processes—not a failure of good people doing extraordinary work.

I am confident that I reflect the sentiment of all hospitals that we are anxious to understand the full set of circumstances involved in this unfortunate incident and put in place improvements that will ensure that it does not happen again.

Thank you for your attention. This concludes our formal statements. We would be pleased to answer questions from the members.

The Chair (Mr. Ernie Hardeman): Thank you very much for the presentation. We will start the questioning with Mr. Yurek.

Interjection.

The Chair (Mr. Ernie Hardeman): Oh, Ms. McKenna.

Mrs. Jane McKenna: Thank you very much. I'd like to thank you so much for coming here today. You should be very proud of your team, like you just said—all teamwork works together—and how grateful the people who were touched by this were that they came and did what they did. So thank you so much. It's wonderful.

My first question is, when did you start outsourcing the chemotherapy drug in question at Peterborough Regional Health Centre?

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Mr. Ken Tremblay: We get the drug through the Durham Regional Cancer Centre program, and it was part of that process that the product appeared. So this was not our decision to outsource. We are the site that receives materials.

Mrs. Jane McKenna: Okay. The contract, I'm assuming, is with Marchese and Medbuy, and not with you?

Mr. Ken Tremblay: That's correct.

Mrs. Jane McKenna: Okay. So did anybody at any time on your hospital staff review that contract?

Mr. Ken Tremblay: No, we weren't part of that process.

Mrs. Jane McKenna: Ms. Zaffiro was in here yesterday from Marchese, and she speculated yesterday that Baxter's drugs were concentration-specific, and she stated very clearly that the drugs provided by Marchese were not concentration-specific. She also said that Marchese's labels were approved by Medbuy. Please, can you explain how these two labels would look and how they would differ for a concentration-specific label and non-concentration-specific label?

Ms. Laura Freeman: As I explained before, the difference between the two labels was, in the Marchese, it stated that gemcitabine was four grams per 100 millilitres, and the Baxter label indicated 4,000 milligrams and went on to total volume of 105.26 millilitres, and labelled as gemcitabine 38 milligrams per millilitre. So the end concentration is on the Baxter bag.

Mrs. Jane McKenna: I guess my question is, if Medbuy had done the contract, put all the information in the contract, why would the chemotherapy that you were getting differ from one company to another? If it's the same—so do you know if it was the same contract that you had with Baxter, or was it changed for some reason?

Ms. Laura Freeman: We were not party to the contract, so we're not aware of that information and have no knowledge of the contracts in either case.

The Chair (Mr. Ernie Hardeman): Mr. Yurek.

Mr. Jeff Yurek: Thank you. I reiterate the competence of your staff. They all deserve a pat on the back for catching this and alerting Ontario to the error that had occurred.

I might go back—my question to start out is with the labelling. We've heard from other hospitals that Marchese won the contract—even Marchese announced—because they had superior labelling, yet what you've shown us is that Marchese had four grams in 100 ml only and Baxter seemed to have had more information on it. Would you agree with previous statements made that Marchese had the superior label?

Ms. Laura Freeman: We were not party to the contract or the evaluation, but we did the comparison on the labelling and the labelling was different between the two products.

Mr. Jeff Yurek: And do you know if the Baxter label that you received was consistent with what they provided the other hospitals in the province?

Ms. Laura Freeman: We don't know.

Mr. Jeff Yurek: Has your hospital been given any direction from the Ministry of Health as to how to work with Medbuy in procuring medications? Any standards or guidelines that you think that they should be following, through the Ministry of Health?

Mr. Ken Tremblay: Not to that degree. Medbuy, HealthPRO and all kinds of shared service organizations to improve the efficiency of the health care supply chain have been in our industry for a long time and, in fact,

through OntarioBuys and the Minister of Finance have been encouraged.

Mr. Jeff Yurek: Yes, the Minister of Finance. But even though this has been ongoing for many years, procurement of compounded medications, it's a growing field just mainly because the amount of staff time—your staff have better uses doing other things than spending hours and hours making certain medications. That's why most likely it gets sent outside of the hospital area. You would think the Ministry of Health would step in and perhaps say, "This is a very important field that we're now entering into, a new dimension in health care that maybe we should provide some guidance and protocol on." What are your thoughts on that?

Mr. Ken Tremblay: I think that's probably going to be at the heart of Dr. Thiessen's assessment of the situation, to give long-term recommendations to the sector or the industry as to how we might want to pursue this. In the past—this has been an issue for hospitals and health care for some time, and every hospital is a little bit different.

Mr. Jeff Yurek: Do you do any other medications compounded outside of the hospital that you receive? Any other classes of medication outside the chemo drugs?

Ms. Laura Freeman: Yes, we do.

Mr. Jeff Yurek: Can you list them for us and who supplies them?

Ms. Laura Freeman: I don't have the exact list available, but we can get that to the committee.

Mr. Jeff Yurek: Is it the same supplier, Baxter, Marchese—

Ms. Laura Freeman: It is with Baxter.

Mr. Jeff Yurek: Baxter supplies all those. Did Medbuy involve you at all in the process that's picking a new supplier when they decided to tender?

Ms. Laura Freeman: They did not. We are part—we receive our drugs through the Durham Regional Cancer Centre, so we're not part of that contract. It's through our relationship with the DRCC.

Mr. Jeff Yurek: Do you think it would be wise to maybe involve the participating hospitals and maybe the Ministry of Health in procuring compounded medications, or medications in general?

Ms. Laura Freeman: When there's group buying, oftentimes there are representative hospitals selected to do the evaluations, so it's not always every hospital that is participating that sits on evaluation committees. So that is standard practice.

Mr. Jeff Yurek: Do you have any knowledge of what pre-qualifications Medbuy would put out in order to allow someone to bid on a product or to produce a product?

Ms. Laura Freeman: We were not party to the whole process, so we do not have that knowledge.

Mr. Jeff Yurek: A general question I've asked others: Your blood products come from a certified, accredited source, your drugs come from accredited, certified manufacturers, and the hips you use in replacements

come from qualified, certified, accredited organizations. Do you not think it would be common sense that your compounded medications also come from a certified, accredited source?

Mr. Ken Tremblay: I think, in the broader sense, that would be the goal of the system, yes.

Mr. Jeff Yurek: And do you not think perhaps that in the RFP tendering process, guidelines would have come from the Minister of Health to ensure that the company that is tendering the product is—

Interjection.

Mr. Jeff Yurek: Sorry, Bill?

Interjection.

Mr. Jeff Yurek: Okay—that the products are coming from an accredited supplier?

Mr. Ken Tremblay: The RFP process is guided by the broader public sector procurement guidelines through the shared services enterprise and these group purchasing enterprises. Those kinds of specifications are usually in the RFP. We don't know that because we weren't part of that one.

Mr. Jeff Yurek: Okay. When stuff changes in the system, that perhaps maybe the government needs to react, I always refer it back to the Internet. When the Internet came to the system, whole new policies and procedures had to be developed because it was something new and it was going to improve the system, much like outsourcing the compounded medications; it's something that's newer and it's going to hopefully improve the utilization of our health care professionals. I think a lot of that direction should have been thought of from one of the aspects of the Ministry of Health in bringing that forward.

I'll save my time for the next round.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Gélinas.

M^{me} France Gélinas: Thank you. I will continue on with what my colleague was saying. First, thank you for being here, and thank you for all of your team. I think, Doctor, you said it best: You were able to catch this because of the culture you have within your organizations, because everybody stepped up to the plate and felt comfortable bringing up issues. We can only thank you and, I guess, cannot thank you enough for what you have done and continue to do.

The chemo drugs come to you through a partnership that you've explained to us that you have with Durham. Basically, you feel confident in the relationship you have with Durham, that when they went out and used group purchasing, they had kind of done due diligence and what you were going to get was what you needed?

Dr. Peter McLaughlin: Yes, we do have confidence in the Durham Regional Cancer Centre.

M^{me} France Gélinas: I take it that, for you, this is a meaningful way to do business. It works good. I mean, you have the shared services with them. The physicians who actually go to your site came and testified earlier on, and it seems to be a good partnership.

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Dr. Peter McLaughlin: Yes, we agree with that.

M^{me} France Gélinas: And is this something that you figure should continue?

Dr. Peter McLaughlin: Yes. I think it's in the best interests of patient care in our region that it continue.

M^{me} France Gélinas: I agree.

We're in the midst of finding out how we can do better, how we can make sure it doesn't happen again, and the Ministry of Health sends this regulation that states that hospitals must not purchase drugs directly or indirectly from an unregulated facility. But you've explained to us that you do not really take part in the purchasing of those drugs; you trusted your partner. What would that mean for you, that from now on, you cannot purchase drugs directly or indirectly from an unregulated facility? You never had the need to go and check because you trusted your partner. But now we've added some checks and balances onto your hospital that do not respect a partnership that is there, that works, that provides quality care for the people of your region. How do we balance the two?

Dr. Peter McLaughlin: As I said, from the patient's perspective, this partnership has resulted in delivery of excellent care over the years. I look forward to Dr. Thiessen's report to recommend appropriate changes in our system to benefit all.

M^{me} France Gélinas: It's weird that we have a Ministry of Health that suddenly starts to issue directives that are not respectful of a process that has served the people of Ontario well. I agree with you that it would be wiser, from the Ministry of Health's perspective, to wait till the results are in rather than issue regulations that would basically force you to completely rework that partnership.

That brings me to this grey area of oversight. I'll ask any of you: Did you know that there was a grey area of oversight in medication preparation?

Mr. Ken Tremblay: No, we didn't.

M^{me} France Gélinas: When did you find out?

Mr. Ken Tremblay: During the course of this review and in the subsequent days following this event, as information became available through your proceedings and the like—more recently, even as of some of yesterday's testimony.

M^{me} France Gélinas: Were you surprised that there was a grey area of oversight?

Mr. Ken Tremblay: In hindsight, yes. I think we're going to look to Dr. Thiessen's recommendations to fill the void, whether it's by regulation or practice or professional performance etc. I don't think we would knowingly purchase from inauthentic sources.

M^{me} France Gélinas: Had you known, things would have been different?

Mr. Ken Tremblay: In hindsight, I think we want to make sure that all of our procurement processes meet the standards expected in the province of Ontario, as regulated—or by reviews such as this. Again, we look forward to Dr. Thiessen's in-depth analysis of the whole

supply chain in this admixture area and the jurisdictional issues that will probably ensue.

M^{me} France Gélinas: I agree. Given what we know now—that it was a grey area of oversight, that that grey area of oversight had actually been identified quite a long time ago—does that make you nervous that there could be other grey areas of oversight within the partners that you depend on?

Mr. Ken Tremblay: I think we're relatively confident in the performance of the health system. We can always improve. It's a large system; it's very complex; it's filled with all kinds of regulations and processes and things like that. Again, we look forward to Dr. Thiessen, who's going to get into the nuances of this, so that on the specific issue about IV admixture and the marketplace, nobody's in that grey area.

M^{me} France Gélinas: If we look outside of drug supply—I mean, in order for you to do your work, you depend on not only drugs, you depend on results coming in from labs and X-rays and blood, all sorts of partners who are community-based partners but who send in vital information in order for the people who work in the hospital to do their work. Any worries there, that outside of drug procurement there could be other areas within the community-based sector that have no oversight?

Mr. Ken Tremblay: I think you're asking for some speculation, and I think we'd be hard pressed to indict any sector of the health industry, in all of its scale, in all of its nuances, in this country. We can always do better in any sector, so we'll be continually diligent and hope that our processes capture these.

M^{me} France Gélinas: Would I be paraphrasing correctly if I say that you basically trust the partners you work with, that there is sufficient oversight, that as complex as it is, the regulations and the oversight are there to allow you to trust your partners and to do your piece of the work?

Mr. Ken Tremblay: I would say yes, and that at its core for us on this episode, it was a good catch, just as it was supposed to do.

M^{me} France Gélinas: The system worked?

Mr. Ken Tremblay: From where we sit on this issue, yes.

M^{me} France Gélinas: I would say I agree. So there exists a grey area of oversight. You're not overly worried that other partners will come out the same way, because we take it for granted that the partners in the health care system do have oversight and that it was a one-off that it didn't happen this way.

How long has Peterborough been outsourcing drugs of any kind?

Ms. Laura Freeman: I'm not certain of the actual time frame of that, but we could check into that and get back to the committee.

M^{me} France Gélinas: Could I ask Ms. Weir if she would know?

The Chair (Mr. Ernie Hardeman): If Ms. Weir's going to answer, she'll need to come up and be sworn in before we get the answer.

Thank you very much, and the Clerk will ask you to either swear or affirm.

The Clerk of the Committee (Mr. William Short): What was your preference, Ms. Weir?

Ms. Brenda Weir: Affirm.

The Clerk of the Committee (Mr. William Short): So if you could just raise your right hand, please. Ms. Weir, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Brenda Weir: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

M^{me} France Gélinas: My question was, for how many years—how long ago did Peterborough start to outsource the procurement of some of their IV drugs?

Ms. Brenda Weir: We have had a contract with Baxter Civa since 2001.

M^{me} France Gélinas: Since 2001? Which drugs did it start with? Were you there at the time?

Ms. Brenda Weir: No, I was not there at the time.

M^{me} France Gélinas: Since you've been aware, have those contracts changed, grown? About how many different kinds of drugs do you subcontract out to Baxter?

Ms. Brenda Weir: I think there's about four classes of drugs on that list.

M^{me} France Gélinas: Okay. I think you already—you didn't, but your colleague testified that you still have a contract with Baxter.

Ms. Brenda Weir: We do.

M^{me} France Gélinas: Okay. It was solely the contract for those two chemo drugs that went to Marchese?

Ms. Brenda Weir: Those drugs are not within the Baxter contract.

M^{me} France Gélinas: Okay. You deal more specifically with pharmacy. Did you know that there was a grey area of oversight in the supply chain?

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Ms. Brenda Weir: No, I did not.

M^{me} France Gélinas: In your experience dealing with drugs that are given to you, IV drugs that are given to you, either by concentration or by full amount, is this something out of the ordinary or is this something you see every day?

Ms. Brenda Weir: I'm sorry; I'm not understanding.

M^{me} France Gélinas: The presentation that was done to us says the Marchese label indicated a total amount—there were four grams of the medication—as opposed to the Baxter's label that indicated a concentration of medication of 38 milligrams per millilitre. What I'm asking you is, those two ways of reporting drugs in an IV medication, is this something you see often?

Ms. Brenda Weir: You'd look for the final concentration of milligram per ml.

M^{me} France Gélinas: In all of the IV drugs that you deal with?

Ms. Brenda Weir: You would look for that, yes.

M^{me} France Gélinas: So for your pharmacy technician, it was—

Ms. Brenda Weir: Assistant.

M^{me} France Gélinas: Sorry. For your pharmacy assistant. What's the difference?

Ms. Brenda Weir: There's a regulation process that they're going through to become registered technicians.

M^{me} France Gélinas: So it was the pharmacy assistant?

Ms. Brenda Weir: Yes.

M^{me} France Gélinas: How big is your pharmacy department?

Ms. Brenda Weir: Staff-wise or—

M^{me} France Gélinas: Yes.

Ms. Brenda Weir: We have 10 pharmacists and about 46 pharmacy assistants and aides.

M^{me} France Gélinas: No technicians?

Ms. Brenda Weir: Not yet. They're in the process of regulating.

M^{me} France Gélinas: Okay, and what's the difference between an assistant and an aide?

Ms. Brenda Weir: An aide does more receiving or—they're not actually mixing the drugs.

M^{me} France Gélinas: Okay, the ones that are mixing the drugs—and of those 10 pharmacists and 46 assistants and aides—how many are, more specifically, for the cancer drugs?

Ms. Brenda Weir: There are four assistants that work with the oncology program.

M^{me} France Gélinas: And no pharmacists?

Ms. Brenda Weir: There are pharmacists but they are DRCC pharmacists.

M^{me} France Gélinas: Okay. So the pharmacists for your oncology programs are with your partner?

Ms. Brenda Weir: Yes.

M^{me} France Gélinas: And then you have four in-house assistants. Okay.

Since you're no longer using Marchese products, how are you dealing with those drugs now?

Ms. Brenda Weir: We're admixing in-house.

M^{me} France Gélinas: In-house in Durham or in-house in Peterborough?

Ms. Brenda Weir: No, in Peterborough.

M^{me} France Gélinas: And you're doing this patient-specific?

Ms. Brenda Weir: Yes.

M^{me} France Gélinas: Okay. The people in Peterborough, when they first saw that there was no concentration but just the total amount, why did it alert them?

Ms. Brenda Weir: Well, they were doing their double-checks to look at—that's what they do to mix their drugs: They have a double-check process.

M^{me} France Gélinas: And when they double-checked, they wanted to see a concentration and they could not find it? That's why they raised the alarm bell?

Ms. Brenda Weir: Yes.

M^{me} France Gélinas: Did you want to ask a question? Okay, go ahead.

Ms. Cindy Forster: Hello. Yesterday I asked a question, not knowing what kind of dosages of chemotherapy agents are for specific patients, whether or not a red flag should have been raised at Marchese with respect to the gemcitabine, is it, the four grams in 100 ml. So my question to them was, was that kind of—they said that they were not requested to prepare concentration-specific doses, and so I asked the question, you know, was four grams per 100 ml a usual single-patient dosage for one chemotherapy treatment? They responded by saying they prepared what they were asked to prepare. The point I was trying to get at was, is that four grams in 100 ml an average dosage for one treatment? Would that have raised a flag for the pharmacist at Marchese, or was it a larger dose than a patient would normally receive for one chemotherapy treatment?

Dr. Peter McLaughlin: I am not an oncologist, so I'm not going to comment on the range of doses of gemcitabine. What is clear in the one patient at Peterborough that we were dealing with: the dose to be given was less than the full bag.

Ms. Cindy Forster: Thank you. I think that was it.

M^{me} France Gélinas: Actually, I think I'm going to let it go around because the next line of questions are completely different.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Chair. On behalf of the government, I'd also like to congratulate your pharmacy assistants for the great work they did in terms of noticing the difference in the labelling and being alert enough to take it further, take it up to the Durham Regional Cancer Centre. I think certainly patients in the Peterborough area can be quite reassured by that very prompt action. Thank you for the chronology as to what happened internally within your own system.

I guess I would say that in terms of notifying the Ministry of Health and Long-Term Care, since you are sort of a subsidiary to the Durham Regional Cancer Centre, I suppose any notification to the Central East LHIN or to the ministry, you would have assumed, was done by them. You didn't think to notify anyone March 20.

Mr. Ken Tremblay: Our notification went to DRCC and then there was a fan-out and a distribution. There's a well-connected network of the professions in these facilities and the word went out quickly and the verification was made—that fan-out—relatively quickly.

Ms. Helena Jaczek: We've been focusing in on the gemcitabine. What about the cyclophosphamide? I know that you put a hold on the use of it, but was that tested at all by your pharmacy assistants?

Ms. Laura Freeman: It was not. We had not depleted the previous supply of that drug, so we hadn't started in to and had not received a new supply.

Ms. Helena Jaczek: So you were still using the Baxter supply.

Ms. Laura Freeman: We were still using the Baxter product.

Ms. Helena Jaczek: In terms of your quality assurance process within your pharmacy, you obviously empower your people to ask questions and we heard quite a bit of that sort of culture from Lakeridge and from Kevin Empey as well, and that's wonderful. But do you have some sort of formal quality assurance process internally related to compounded drugs?

Ms. Brenda Weir: We do. We follow the Central East LHIN admixture guidelines.

Ms. Helena Jaczek: Could you elaborate on what those admixture guidelines are?

Ms. Brenda Weir: Those are guidelines that have been prepared with representatives from the hospital within the Central East LHIN, which they follow. They're based on best guidelines throughout Canada and the BC manual. There's about 20 references.

Ms. Helena Jaczek: Obviously, having discovered the problem with gemcitabine, you can say with confidence that you're happy with the safety of the drug supply provided through Peterborough regional hospital. Is that correct?

Dr. Peter McLaughlin: Yes.

Ms. Helena Jaczek: Thank you. I think part of what we have talked about in this committee is that our concern is for those patients out there. Just for the record, we want to reassure people, certainly in your area, that you have a good quality assurance program.

When Baxter was the recipient back in I think you said 2001, Ms. Weir, was Peterborough hospital involved at that time with that outsourcing?

Ms. Brenda Weir: Yes, and that would be outside of the oncology program.

Ms. Helena Jaczek: And at that time, you were using direct purchasing, or did you use Medbuy? Would you recall or would you know?

Ms. Brenda Weir: That would be through direct purchasing.

Ms. Helena Jaczek: It was through direct purchasing. So when the move came as part of Durham Regional Cancer Centre that they would look after the chemotherapeutic drugs, was there any consultation with Peterborough in terms of what that would look like? It sounds like you just trusted them to do the right thing.

Mr. Ken Tremblay: It's a bit of that. It's also the governance of a shared regional program through the memorandum that exists in the cancer care model, that you have a regional centre and then organizations that support it through the management of patients and all those things. The MOU contemplates a variety of responsibilities for both parties, and on this particular side, it's the provision of supplies, which, in this case, would include those drugs. Other things—miscellaneous expenses, med-cert supplies—would be covered in other parts of normal operations.

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Ms. Helena Jaczek: I'm going to just turn to the grey area. Ken, you and I have been around Ministry of Health people for longer than we both choose to remember, probably. You've said that you did not know this was a

grey zone. Do you ever remember, in your many dealings with the ministry, any sort of conversations around the subject of compounded drugs and regulation, accreditation or anything like that?

Mr. Ken Tremblay: Well, actually, Accreditation Canada contemplates that best practice is—especially for those sites that might have low volumes—to contemplate outsourcing for quality assurance, because it's small doses and small sites with little infrastructure or capacity to put some of these very complex medication series together—that actually contemplates as an accreditation standard that that in fact be the direction. All the parties of the health system are part of the formation of accreditation guidelines, so I'm sure we were all aware of that. The notion of a regulatory grey zone is new.

Ms. Helena Jaczek: Is new?

Mr. Ken Tremblay: Yes.

Ms. Helena Jaczek: So you were never party to conversations related to that.

Mr. Ken Tremblay: No.

Ms. Helena Jaczek: So now that you have heard, as we've all heard, that there is this grey zone between Health Canada and the College of Pharmacists, do you feel that the government's actions to date are reassuring in terms of the regulation that is proposed—the formation of the working group and Dr. Thiessen's review?

Mr. Ken Tremblay: The regulation is out for consultation in the broader system to make sure that it's applicable to all sites and settings. As you can imagine, there's quite a broad range of practice out there, so one regulation that meets all the needs of all the users in all the settings all of the time would be a challenge.

Dr. Thiessen et al. will obviously give advice and counsel on the regulatory framework, the jurisdictional overlap or gaps as they might exist, in order to safeguard the supply chain and admixtures. We look forward to that work. I think it's necessary work. And if it is a grey zone, then we should turn it to black and white and understand those accountabilities and responsibilities.

Ms. Helena Jaczek: Have you been a part of the working group that the ministry put together?

Mr. Ken Tremblay: I am on that working group, and we were one of the first sites that Dr. Thiessen visited to sort of get a good grounding on how this issue emerged, evolved and morphed over time.

Ms. Helena Jaczek: And are you finding that dialogue helpful and useful?

Mr. Ken Tremblay: I think it's, among the four sites, making sure that we're all concentrating on the public and the patients affected, giving advice and counsel in terms of process. The regulation is a good start, but I think it will be finessed by Dr. Thiessen's advice and counsel and the broader consultations of the system.

This is a large piece of the Canadian health care system. We want to make sure that all of its pieces are embraced in it, because there could be parts that create gaps somewhere else, duplications somewhere else or another kind of issue unintentionally.

Ms. Helena Jaczek: Yes.

We'll save the rest of our time.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. McKenna?

Mrs. Jane McKenna: Yes. My first question is, were you concerned about the gap that clearly was evident? We had, again, Ms. Zaffiro from Marchese here yesterday, and she said that when she was awarded the RFP, she clearly got on the phone—it was documented today that her facts were true—with the College of Pharmacists and also with Health Canada, asking to be regulated, because she was going to separate that part of her company because of this RFP that she had won.

This woman clearly realized there was a problem and picked up the phone to find out how she could be on top of it. Was there any time at all that you were concerned about the gap, and if you were, did you talk to the Minister of Health and Long-Term Care? That, to me, would be a red flag.

Mr. Ken Tremblay: We all, as a system, found that out yesterday, so I don't think we want to speculate on that. The conversation on what happened would certainly not be at our level in the system.

Mrs. Jane McKenna: Okay. Just as the CEO of a hospital, though, I guess that's—just listening to everything that's been going on here and sitting here on this committee, I guess another question I have is, who gives the direction to Medbuy to do the contract?

Mr. Ken Tremblay: The Medbuy buying group would give that direction based on those hospitals participating that would see the advantages of a collective RFP or bidding process. In this case, it was, I gather, four, and they chose to go to market with that product and volume as a discrete project. And we weren't part of that, so—

Mrs. Jane McKenna: So there's no oversight from you at all. When that contract gets put together from Medbuy—which is a broker; it's not a pharmacist or a hospital. They do that themselves. So they're solely responsible?

Mr. Ken Tremblay: They are the sponsor of that cancer program in our region.

Mrs. Jane McKenna: Okay. Go ahead.

The Chair (Mr. Ernie Hardeman): Mr. Yurek.

Mr. Jeff Yurek: So your relationship with Medbuy is basically—

Mr. Ken Tremblay: We don't have a relationship with Medbuy.

Mr. Jeff Yurek: You don't have any relationship. So Durham regional coordinates the purchases through Medbuy for you; is that—

Mr. Ken Tremblay: I'll maybe let Laura talk to that, but they issued that process.

Ms. Laura Freeman: That's correct. Durham Regional Cancer Centre does the procurement of our chemotherapy drugs.

Mr. Jeff Yurek: So they do it for your hospital and others in the group?

Ms. Laura Freeman: I assume so.

Mr. Jeff Yurek: So why would you have to use Medbuy, then, at all? If already a group of hospitals have come together to coordinate procurement, why couldn't

Durham regional deal directly with Baxter or Marchese to come to some sort of contract?

Ms. Laura Freeman: Durham would have to answer that question because the procurement of the chemotherapy is through them.

Mr. Jeff Yurek: I was just thinking why—was there a need to actually use Medbuy at all in that service? Couldn't it have been handled by the group of pharmacies themselves—

Mr. Ken Tremblay: The Canadian public enjoys volume discounting through supply chain strategies, in many cases underwritten by the provincial governments. So whether it's Medbuy, HealthPRO or other shared service organizations that precede it, economies of scale by collective action benefit the price point of various products in the system. So that's how these HealthPROs and Medbuys were created.

Mr. Jeff Yurek: I've heard the LHIN mentioned a few times, but no one has yet to give me an answer. What role does the LHIN have in any of this situation?

Mr. Ken Tremblay: You'd have to check the details of their legislation, but largely it's funding and oversight at the macro level.

Mr. Jeff Yurek: So the oversight—

Mr. Ken Tremblay: General operations, not detailed—so system planning, capacity, distribution, population health, those kinds of issues.

Mr. Jeff Yurek: So they weren't really involved at all with this problem?

Mr. Ken Tremblay: No.

Mr. Jeff Yurek: Would you be in favour of allowing the OCP to regulate and oversee your hospital pharmacies?

Interjection: They do already.

Mr. Jeff Yurek: In-hospital, not the outpatient pharmacies.

Dr. Peter McLaughlin: If that's the wisdom of the policy-makers, we will be happy to accept it.

Mr. Jeff Yurek: Just your opinion. It won't be held against you.

Dr. Peter McLaughlin: This is a complex area. It would be presumptuous of me to name any body that would be better than any other body to do the job that needs to be done, and I would hope that Dr. Thiessen would make a recommendation that would inform us on the best regulation. But again, from clinicians on the ground, we welcome good regulation, and our job is to have the policies and procedures that will support that regulation to do the job that needs to be done for the patients.

Mr. Jeff Yurek: I just asked that because, right now, even hospital pharmacists don't really have to be associated with the College of Pharmacists if they choose not to, unless they go and work out in the community or do something else. There's talk about bringing hospital pharmacists under the College of Pharmacists, and now you have perhaps a college of pharmacy following hospital policy and an Ontario college of pharmacy policy, and the two are going to maybe bump heads some

time down the road, so I'm looking out to the future. Who's going to supersede who? At the end of the day that would be the question to throw out there.

Dr. Peter McLaughlin: I would say that's a very good question and there are people wiser than me that will be able to answer that as this goes ahead, I'm sure.

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Mr. Jeff Yurek: I'll save my time for the next time around.

The Chair (Mr. Ernie Hardeman): Okay. Thank you very much. You have about two minutes.

Ms. Gélinas?

M^{me} France Gélinas: I think my question will be for you again, Mrs. Weir. I'm curious to see—on March 20, at 2:20, a pharmacy assistant notices a difference. You must have had patient appointments booked for the rest of that day. Cancer treatment programs tend to be pretty busy until the end of the shift. Do you know if anybody had a missed appointment, as in you had run out of the Baxter drug, you start the new supplier, and you find yourself having to cancel appointments or to reschedule?

Ms. Brenda Weir: There were no cancelled appointments.

M^{me} France Gélinas: There were no cancelled appointments.

In your hospital, only one person was found to have received one of the two drugs. Am I right?

Ms. Brenda Weir: Yes.

M^{me} France Gélinas: And that person was notified, you've already told us.

Two things. The first one is, except for chemotherapy drugs and cardiac drugs, do you usually deal in concentration of medication, or do you usually deal in actual amount?

Ms. Brenda Weir: It's concentration.

M^{me} France Gélinas: It's concentration all the time?

Ms. Brenda Weir: Concentration.

M^{me} France Gélinas: So the people who work in your pharmacy know to look for the concentration of the medication on the different IV bags that they get.

Ms. Brenda Weir: Yes.

M^{me} France Gélinas: And that's not only for cancer and cardiac; it would be for other IV drugs as well?

Ms. Brenda Weir: Concentration.

M^{me} France Gélinas: Even if you were to give a prescription for antibiotics, it would be by concentration?

Ms. Brenda Weir: Are you talking about injection or—

M^{me} France Gélinas: Drip—I'm talking IV.

Ms. Brenda Weir: It's usually by concentration.

M^{me} France Gélinas: By concentration. Okay.

It looked like you wanted to add something.

Dr. Peter McLaughlin: From the physician's point of view, the total amount of drug would be prescribed. The administration through the formulary would then rely on nursing and concentrations to achieve that total dose in a reasonable volume.

M^{me} France Gélinas: Okay, so you basically always, though, deal with concentration at your end. At the

doctor's end, he wants a certain amount, and then at the pharmacy end they use the concentration in the right amount of liquid to make sure that they meet whatever the prescription was.

Dr. Peter McLaughlin: That is correct.

The Chair (Mr. Ernie Hardeman): Thank you very much. That does conclude your time.

Ms. Jaczek.

Ms. Helena Jaczek: How much time do we have?

The Chair (Mr. Ernie Hardeman): Nine minutes.

Ms. Helena Jaczek: Excellent.

We're fairly confident now, with Health Canada involved, the college of pharmacists of Ontario and Dr. Thiessen's report and so on, that this grey zone is no longer going to be grey. There will be regulation. Those companies involved in compounding will be regulated etc.

I would like to ask a little bit more about outsourcing. Ken, again, in your experience, what are the benefits of outsourcing in general? You've alluded to economies of scale. Can you just sort of give us more on that?

Mr. Ken Tremblay: The theory and practice of outsourcing 101 is largely to achieve economies of scale or to get some additional benefit, either through that scale or infrastructure. This chemo issue was done in a semi-sterile technique: fume hoods, very expensive infrastructure, very highly trained individuals that need sufficient volume to maintain their skills and proficiency. There's technology involved that has to be maintained, software etc. So when you are faced with some threshold volume, you decide whether, in the overall cost-benefit, risk-reward clinical management—you try to make those decisions. We put those people in a room together and we ask them to evaluate these various scenarios, and that ultimately culminates in a recommendation to either insource or outsource. It varies all the way from information technology to utilities to consumables and, in this case, admixtures. Every large organization, I think, goes through that decision tree.

Ms. Helena Jaczek: I know my colleague wants to ask a question, but I just want to follow up with what you said. So you don't see in the future, because of this particular incident, that you're going to back off in general related to outsourcing?

Mr. Ken Tremblay: We will continue to use the diligence necessary to make those decisions in the best interests of patient care, efficiency, economy, safeguards, critical mass and a variety of other criteria. We are under incredible pressure as a health care system to make the tax dollars go further and, where we can, to get those savings passed on to either capacity or new programming as Ontario grows. So from a theoretical perspective, no, this is not a deal-breaker, but it certainly widens our eyes in terms of the nuances and the issues associated with this decision.

Ms. Helena Jaczek: Mr. Mauro.

The Chair (Mr. Ernie Hardeman): Thank you very much. Mr. Mauro?

Mr. Bill Mauro: Thank you, Mr. Chair. I've been subbed on this committee; I'm playing a bit of catch-up

here. Ms. Weir, you said that in 2001 the contract came into place with Baxter. Is that accurate?

Ms. Brenda Weir: Baxter CIVA, yes.

Mr. Bill Mauro: And previous to that, Peterborough directly procured that product?

Ms. Brenda Weir: I don't know. I wasn't employed at Peterborough at that time.

Mr. Bill Mauro: Is there anybody who would know the answer?

Mr. Ken Tremblay: No.

Mr. Bill Mauro: So we don't know?

Mr. Ken Tremblay: We don't know.

Mr. Bill Mauro: Okay. I was interested in your answer earlier, Mr. Tremblay, when there was a question for you from the third party about outsourcing. In your case, Durham Regional Cancer Centre procures the product for you. I thought it was interesting: You kind of turned the argument on its ear a bit and made it sound like there are many examples, especially for smaller hospitals—I come from northern Ontario and we have a number of smaller hospitals relative to what we might find in the GTA—where the outsourcing to an organization like Durham Regional Cancer Centre, or we have a very robust cancer centre in my hospital in Thunder Bay, could actually lead to an enhanced level of accountability and quality assurance. I think that's what you said; that was your point. Is that fair of me to say?

Mr. Ken Tremblay: Yes.

Mr. Bill Mauro: The point being that many small hospitals don't have the time, the staff, the expertise necessary to provide quality assurance for a variety—in this case, we're talking about the chemotherapy drugs. I would assume there would be other examples that, as a hospital professional, you could probably give us where it actually provides a safer system for the patient and a better sense of safety for the hospitals themselves.

Mr. Ken Tremblay: Our industry tends to work on the adage that the more you do, the better you get. It's a critical mass issue, that at certain thresholds of volume there's a better likelihood of a good result because you do so many. We have to always look at the competencies, the skills, the volumes necessary to maintain that proficiency and to safeguard that in the interest of clinical care and all the other variables.

Mr. Bill Mauro: So with the Durham Regional Cancer Centre, which was procuring the chemotherapy drugs, this was a publicly funded organization with specialized skill sets that was procuring chemo drugs for a variety of health care providers?

Mr. Ken Tremblay: Through their contracts and their own group purchasing strategies, either Plexxus or Medbuy.

Mr. Bill Mauro: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Jaczek?

Ms. Helena Jaczek: Yes. How are you preparing these products now or how are you acquiring them?

Ms. Brenda Weir: They're actually being admixed in the hospital right now.

Ms. Helena Jaczek: So they're being admixed in your hospital.

Ms. Brenda Weir: Yes.

Ms. Helena Jaczek: Not Durham; right there. Are you finding it a very time-consuming process, or how—what's the difference now?

Ms. Brenda Weir: They're building it into their day-to-day activities in the area.

Ms. Helena Jaczek: So you haven't had to hire more staff?

Ms. Brenda Weir: No.

Ms. Helena Jaczek: You're able to cope with the volume that you have.

Ms. Brenda Weir: Yes.

Ms. Helena Jaczek: And you have a pharmacist overseeing the admixing?

Ms. Brenda Weir: There's a pharmacist there for consultation, yes.

Ms. Helena Jaczek: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you, and that's complete. Mr. Yurek, if you have nothing further, thank you very much—

Interjection.

The Chair (Mr. Ernie Hardeman): You have a comment, Ms. Gélinas?

M^{me} France Gélinas: No. I was hoping to be able to use some of the time. Those people travelled a long way. I might as well talk to them while they're here.

The Chair (Mr. Ernie Hardeman): Well, that would have to be unanimous consent from the committee, because the times are pretty strictly set here.

M^{me} France Gélinas: It would be a very short question.

The Chair (Mr. Ernie Hardeman): Do you we have unanimous consent to have another question? Mr. Yurek, you have two minutes left.

M^{me} France Gélinas: You're willing to share your two minutes with me?

Mr. Jeff Yurek: If the government agrees, sure.

The Chair (Mr. Ernie Hardeman): Okay. We'll allow the question.

M^{me} France Gélinas: One question, and it shouldn't be a too hard one. You were the one least impacted, if you look at the number of patients. You testified that you only had one patient who received a diluted amount of drugs. My question is, although the facts are there, that there was only one patient, have you noticed an impact on the rest of the oncology patients? Have you noticed an impact on the rest of the people who you help in your hospital?

Dr. Peter McLaughlin: In our hospital, and amongst our staff, I would say there's a sense of pride about the pharmacy staff. I would have concern, as a physician, that this entire incident province-wide would raise concerns among patients, patient groups as a whole, about the pharma agents that they are getting. I think that's why it's important to complete Dr. Thiessen's review to change our system in whatever way makes sense, to assure our entire public that our drug delivery system is as safe as it can possibly be.

The Chair (Mr. Ernie Hardeman): Thank you very much. It does conclude the time and the inquisition.

With that, the committee will reconvene at 2 o'clock on Monday. With that, the committee is adjourned.

The committee adjourned at 1712.

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Lundi 6 mai 2013

Standing Committee on Social Policy

Oversight of pharmaceutical
companies

Comité permanent de la politique sociale

La surveillance, le contrôle et la
réglementation des entreprises
pharmaceutiques



Chair: Ernie Hardeman
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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 6 May 2013

Lundi 6 mai 2013

*The committee met at 1400 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIES

The Chair (Mr. Ernie Hardeman): I call the meeting of the social policy committee to order. We're meeting again today for a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies. The first is Medbuy today.

Just for the committee's information, we only have two delegations today; the third one was Health Canada, who were unable to make it today. They have sent in a letter answering a number of the concerns that they knew about, and we can have a discussion at some point after the committee has read the letter as to how they wish to proceed—if that's enough information for them, or if they would like us to continue working on trying to get a time set up to hear from Health Canada.

MEDBUY

The Chair (Mr. Ernie Hardeman): With that, we will start with Medbuy. We have them sitting at the table at the front. We thank you very much for being here this afternoon. Before we start the meeting, we will ask you to be sworn in or affirmed in giving testimony before the committee. We'll turn that over to the Clerk.

The Clerk of the Committee (Mr. William Short): I'll go left to right. Mr. Blanchard, if you'd just raise your right hand, please. Do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Michael Blanchard: Yes, I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Mr. Nicholson, same thing; thank you. Mr. Nicholson, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Kent Nicholson: Yes, I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we will, as we have done with other

delegations, give you the opportunity for 20 minutes to make a presentation as to your involvement, shall we say, with the process. Then we will have questions from the three parties. This time, the questions will start with the third party, I believe. I stand to be corrected, but—

Interjection.

The Chair (Mr. Ernie Hardeman): Right again: The third party is first this time, and then we'll make the rotation on that.

With that, I turn the floor over to you to make your presentation.

Mr. Kent Nicholson: Great, thank you. Just by way of orientation, you should have a copy of our opening statement. Additionally, there is a document that is called "Key Documents," and we will in our opening statement draw attention to a number of tabs that are contained therein. We had sent out the information on Friday; I believe it got distributed this morning. So, unfortunately, you don't have the benefit of a lot of preparation, but we'll take our time in terms of describing our opening comments.

I'm going to read the opening statement. I've kind of broken it into four areas. Firstly, we'll touch on a little bit of background in terms of Medbuy: who we are, and the nature of the work that we do. Then we wanted to touch on the request-for-proposal process that supported this particular sourcing initiative. We'll touch on the contract specifically, and we'll also share our knowledge of the events leading up to the issue being identified.

Moving to the prepared statement: By way of background, my name is Kent Nicholson. I'm the president and chief executive officer of Medbuy Corp., and have been since October 2011. With me today is Michael Blanchard, who is our vice-president of pharmacy, clinical services and business development. Michael is a licensed pharmacist and joined us in February 2013. Though Michael just joined us in February, he has over 30 years of pharmacy experience in both hospital and group-purchasing settings.

We begin by expressing our sympathies to the patients and their families that have been affected by the recent news concerning chemotherapy medication in Ontario and New Brunswick. We're committed to assisting in the determination of why this medication error occurred.

We are a national health group purchasing organization, or GPO, that works on behalf of publicly funded and accountable health care organizations in Canada.

These health care organizations comprise the Medbuy membership—or “members”—and are also shareholders of Medbuy.

Medbuy has been in existence since 1989. As a GPO, we aggregate the purchasing power of our members to obtain the best value from suppliers for a wide range of medical supplies, services and pharmaceuticals. The nature of the work that we do tends to drive a higher level of standardization by the hospitals, cutting costs and reducing product variation.

Patient safety is always the focus of our work. We bring together clinical experts from among our members, who work with our staff to make determinations regarding products and services that members ultimately purchase. Our expert member committees are actively engaged and participate in all aspects of our sourcing initiatives.

Medbuy is a share capital corporation registered in Ontario. We operate similarly to a not-for-profit, in that we do not retain earnings. Any revenue that we generate is distributed to our member hospitals in proportion to their spend under Medbuy contracts. In 2012, members' spend against Medbuy contracts totalled \$627 million. Since our inception in 1989, we have saved our members hundreds of millions of dollars that have been redirected to provide front-line patient care.

We are compliant to the Broader Public Sector Accountability Act, meaning that we are governed by the laws that apply to the purchase of goods and services using public funds, and aim to ensure fair, open and competitive procurement practices.

Turning to the request for proposal: In 2008, as part of our role as a GPO, we issued a request for proposal, or RFP, for pharmaceutical products. This RFP included, for the first time, sterile preparation compounding services, or compounding. Medbuy and its members had been considering seeking a compounding contract since 2005. We were encouraged by our members to include compounding in the 2008 RFP, since many member hospitals were already outsourcing their compounding services.

The central consideration when deciding whether it is best to perform compounding in-house or through a third party provider is patient and employee safety. We received only one submission in response to the compounding portion of our 2008 RFP from Baxter. Thus Baxter was awarded the contract, and provided compounding service to participating members from 2008 until 2011.

In early 2011, with the Baxter contract due to expire, we made a public posting announcing that we would be renewing our contract with Baxter for compounding services since, to our knowledge at that time, Baxter was the sole provider of this compounding service. Marchese Health Care, or Marchese, objected to this since it believed it could also provide compounding services. In order to determine whether Marchese did in fact have the facilities and expertise to provide compounding services, some of our staff attended a Marchese facility. After the

visit, we reported back to our pharmacy committee, and together we were satisfied that Marchese could in fact provide compounding service.

As a result, we posted the RFP in 2011 for compounding services. Deadline for RFP submissions was November 9, 2011. We received submissions from three proponents: Baxter, Gentès and Bolduc, and Marchese. The RFP listed a mandatory criterion requiring proponents to warrant that all compounding services would be supervised by licensed pharmacists. This requirement and all other evaluation criteria were determined after a review of existing practices, regulations and policies by member committees and our staff.

In accordance with the Broader Public Sector Accountability Act, our RFP ensured a fair and transparent process that was free of bias. Proponents were scored against a predetermined set of criteria. All submissions were scored independently by subject matter experts from member hospitals, eliminating group bias. The scoring criteria were developed by a committee made up of clinical experts from member hospitals in conjunction with our own internal pharmacy experts.

Scoring criteria were based on four categories: pharmaceutical, label, financial and business. The pharmaceutical and label scores were each assigned a maximum of 30 points; the financial score was assigned a maximum of 25 points; and the business score was assigned a maximum of 15 points.

The contract award was made to the proponent with the highest overall score. Spreadsheets reflecting the scoring process for this particular procurement are found at tab 1 of the document brief we have provided. Even a brief review of these documents demonstrates the detail and exhaustive process of evaluating submissions.

Compounding by third party providers has been available in Canada for over 25 years. As I have noted, the central consideration when outsourcing compounding is patient and employee safety. For this reason, we have been particularly attentive to the requirements we included in both the RFPs we have issued for this service and the contracts we have executed with suppliers. The mandatory requirement that compounding services be performed under the supervision of a licensed pharmacist is of paramount importance to us and our members.

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Marchese satisfied this requirement and warranted that 100% of the pharmacists performing compounding services were licensed in Ontario. In addition, Marchese made the following representations in its RFP submission:

—that it was a pharmacy licensed by the Ontario College of Pharmacists, which enabled it to provide infusion services in compliance with the Ontario Drug and Pharmacies Regulation Act;

—that it provided training to pharmacists in addition to that they received in school, such as the in-house sterile preparation certification program which adheres to the Ontario College of Pharmacists' model standards of practice, the Canadian Intravenous Nurses Association's

standards for infusion therapy, the Canadian Society of Hospital Pharmacists' guidelines, and other professional Canadian and US standards;

—that all staff receive annual recertification of an in-house sterile preparation certificate program;

—that it met United States Pharmacopeia 797 standards for sterile admixing services;

—that it had consulted with Health Canada regarding whether any additional requirements were needed to meet Health Canada regulations; and

—that its infusion technicians had undergone the Chemocheck training and certification program.

In addition, as part of their RFP submissions, proponents were required to submit copies of their proposed labels for scoring. Labels were scored against the precise label-scoring criteria shown at tab 2. The labels that Marchese submitted with its RFP were concentration-specific, meaning that they showed the concentration of the active ingredient, as required by the scoring criteria for labelling. These are found at tab 3A.

Marchese received the highest score on its RFP submission and was, therefore, awarded the contract. The RFP submission, signed by Marchese, is at tab 4. The signatures of Marchese are shown in appendix 1 of its submission.

Although Marchese started using the trade name Marchese Hospital Solutions on some occasions following the contract award, as can be seen on its labels in tab 3B, the name Marchese Health Care continued to appear on many of the communications to and from Medbuy. Our understanding was, and remains today, that the contract is with Marchese Health Care.

Turning to the contract itself, we signed the contract with Marchese for compounding services in February 2012, referred to going forward as “the contract.” A copy of the contract can be found at tab 5. Attached to the contract was a product and pricing list, which lists all the medications that Marchese would be preparing at the request of member hospitals. The list contained the same specifications for the relevant chemotherapy medication that was used in the previous contract with Baxter in 2008. Both lists are attached to tab 6. Baxter never experienced any difficulty in understanding these specifications or in delivering products that matched them.

Even after the award of the contract, we undertook ongoing monitoring of Marchese's performance. In November 2012, a group of our staff and members visited Marchese's Mississauga facility to ensure quality control. Marchese followed this visit with a letter to Medbuy dated December 5. In that letter, Marchese ensured that, “Marchese has a current and valid certificate of accreditation from the Ontario College of Pharmacists.” This letter can be found at tab 7.

Turning now to the discovery of the chemotherapy medication error: On Friday, March 22, 2013, at approximately 5 p.m., we were informed by the director of pharmacy at London Health Sciences Centre that a potential problem had been identified at Lakeridge Health with the concentration of two chemotherapy medications. We immediately initiated inquiries that afternoon.

On the morning of March 25, 2013, we followed up by contacting both Lakeridge and Marchese to further investigate this issue. Marchese agreed to notify all users of these two products and inform them of the potential problem. Marchese also agreed to develop a solution and circulate a communication to the affected hospitals, advising them both of the problem and of the solution.

On Wednesday, March 27, we were advised by Marchese that it had verbally notified all members who purchased these medications of the issue. A written communication, prepared by Marchese, was sent out to our member hospitals on March 28, 2013. Since this issue was first raised, we have been in frequent contact with our members and other interested stakeholders.

In conclusion, we are committed to assisting with any and all investigations regarding why this issue occurred and will co-operate to make sure all of the issues are addressed. We want to do everything that is necessary to ensure that this does not happen again.

The Chair (Mr. Ernie Hardeman): Thank you. Yes, sir? Did you want to speak too?

Mr. Michael Blanchard: No, I'm good. Thank you.

The Chair (Mr. Ernie Hardeman): Oh, okay. I just saw your microphone come on so I thought maybe I had missed something. With that, we will start the questioning with the third party and France Gélinas.

M^{me} France Gélinas: Thank you, Mr. Chair. Thank you for coming. My first question is just a technical one. Mr. Blanchard wasn't there when the contract was being put together. Who would have been the pharmacist from Medbuy at the time?

Mr. Kent Nicholson: Michael has replaced a gentleman by the name of Richard Jones. Richard is also a pharmacist by training. Richard is currently the director of pharmacy at the Vancouver Island Health Authority.

M^{me} France Gélinas: Very good. Another little clean-up issue is on page 2—I don't know if you have the same pages—request for proposal, paragraph number 10. You say that you sent some people: “some of our staff attended at a Marchese facility.” Which facility did they attend, do you know?

Mr. Michael Blanchard: I believe, in my reading of the documents, that it was the facility in Mississauga—pardon, in Hamilton.

M^{me} France Gélinas: In Hamilton, so not the facility where the compounding was going to happen.

Mr. Michael Blanchard: There were a couple of visits. Are you referring to—

M^{me} France Gélinas: Paragraph 10. You go on to say: “Baxter was the sole provider of this compounding service. Marchese Health Care (‘Marchese’) objected to this since it believed it could also provide compounding services. In order to determine whether Marchese did, in fact, have the facilities and expertise to provide compounding services, some of our staff attended at a Marchese facility.”

Mr. Michael Blanchard: If I recall correctly in my reading of the documents that I reviewed, Marchese has

several facilities. They did, at that time, visit a facility in Hamilton.

M^{me} France Gélinas: Hamilton, which is not the facility that would be doing the compounding.

Mr. Kent Nicholson: I'm not sure. If, at the point in time that we were—again, this was before we even launched the RFP—I'm not sure at that point in time if Marchese had determined where they would manufacture or undertake this admixing. The intention was to see a typical facility to give some assertion that, in fact, they were in the compounding business and to give us a sense as to the quality of their facilities and their operation.

M^{me} France Gélinas: Okay. Then I go to page 3, paragraph 17, talking about labels. Second sentence: "Labels were scored against the precise label scoring criteria shown at tab 2. The labels that Marchese submitted with its RFP were concentration-specific, meaning that they showed the concentration of the active ingredient, as required by the scoring criteria...." They had shown you a label that was concentration-specific when they bid on the RFP, but when they supplied the chemo drugs, it was not so. Where was this check supposed to be done, that what they had bid on was actually what they delivered?

Mr. Michael Blanchard: If I understand your question, you're asking about both sets of labels: the labels that they submitted for their RFP and the labels that they subsequently began using when they delivered the product to the customer. I believe both sets of labels have an accurate and specific expression of concentration on both.

M^{me} France Gélinas: That's not what we heard. We heard that the concentration was not specific, as in, it had the total milligrams of the active compound within the saline, not the percentage.

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Mr. Michael Blanchard: If you refer—and I can't remember the tab.

Interjection: Tab 3.

Mr. Michael Blanchard: Tab 3. If you'd take a look at tab 3, as an example, the cyclophosphamide—

Interjection.

Mr. Michael Blanchard: The first page on tab 3B. These are the labels that they utilized after they started providing the service. If you take a look at the cyclophosphamide, for example, which is approximately the third row of labels from the top, the two on the far right side of the page: "Cyclophosphamide 4 g in 200 mL." That is an expression of concentration: two grams in a specific volume. That is the—

Ms. Cindy Forster: What about the other drug, the—

Mr. Michael Blanchard: Gemcitabine?

Ms. Cindy Forster: Yes.

Mr. Michael Blanchard: The same situation. I can find the label for you. We should have it here. If you turn the page over, the first label on the third row from the top: "Gemcitabine 4 g/100mL"—an expression of concentration.

M^{me} France Gélinas: So from the get-go, when they submitted, they actually used the label that they would be using for the year where they supplied diluted chemo drug, and nobody noticed that if you are to label that way, you are not guaranteeing the concentration of the active ingredient.

Mr. Michael Blanchard: I'm not sure if I understand your question, but both the labels that we received for the submission and those that were changed—both sets of labels equally express the specific accurate concentration. I'm not sure if I'm answering your question. Can you maybe rephrase?

Ms. Cindy Forster: Well, my understanding from some of the other people we've heard from is that when Baxter supplied labels, it would say "gemcitabine, five milligrams per millilitre." So four grams in a 100 millilitres and that equals 25 milligrams per millilitre or whatever that calculation is.

Mr. Michael Blanchard: There are some hospitals or members that—you know, there is redundancy in terms of the expression on a label of concentration. So you may express it as two grams in 100 millilitres or 20 milligrams per millilitre, but they're both expressions of concentration of identical specificity.

Ms. Cindy Forster: But if you were actually using these bags of admix drugs for more than one patient, then someone has to do a calculation—

Mr. Michael Blanchard: Yes.

Ms. Cindy Forster: —if the drug is expressed in this way on the label. So whoever that is, the pharmacy technician or the—

Mr. Michael Blanchard: Well, again, a qualified pharmacist. Most oncology products—a specific dose for a patient varies from patient to patient. It may even vary from week to week for the same patient. So when the physician decides on a drug dose, there is always a calculation, no matter what the expression of concentration is. What is key is that you do need an expression of concentration. If the dose is 625 milligrams, if the expression is 20 milligrams per millilitre, you still need to make a calculation. If the expression is 2,000 milligrams per 100 millilitres, you still have to make a calculation. So qualified pharmacists, that's part of their job. It's part of the act of or the art of pharmacy.

Ms. Cindy Forster: Thank you.

M^{me} France Gélinas: Okay. So with this train of thought, were the drugs that were used diluted?

Mr. Michael Blanchard: The drugs in question, both the gemcitabine and the cyclophosphamide, are approved for sale in Canada. They're available in a vial in a powder form. So there is a reconstitution and dissolution of the powder in the vial, and that volume is then transferred into a bag. That's what you mean by diluted?

M^{me} France Gélinas: No, I mean: Why do you think you're here today?

Mr. Michael Blanchard: Why am I here today? Well, simply that the issue or problem is not the concentration or the expression of concentration; there is an expression

of concentration on the labels. The problem is that the labels do not accurately describe the contents of the bag.

M^{me} France Gélinas: The label did not accurately describe the contents of the bag when they responded to the RFP.

Mr. Kent Nicholson: I would suggest that all of the labels they submitted with the RFP and the labels that came subsequently are an exact expression of concentration. When you say it's four grams in 200 millilitres, that's an exact expression of concentration. Our member hospitals relied on that representation. They received the product, they assumed, understandably, that the contents in the bag matched the label. If, in fact, the contents in the bag had matched the label, we wouldn't be here today. It's an issue that the representation on the label is inaccurate, but it is an exact expression of concentration.

The four affected hospitals all independently reviewed the label, interpreted it as an exact expression of concentration and relied on the accuracy of the label to administer to patients.

M^{me} France Gélinas: So the fact that a 200-millilitre bag, once you add the diluted substance in it, no longer has 200 millilitres in it—that never occurred to anybody?

Mr. Michael Blanchard: I would defer that to Marchese. We essentially hosted any RP and requested a specific product to be manufactured according to our description and our specs, which are represented by these labels.

We engaged the services of qualified pharmacists, licensed pharmacists, in an accredited pharmacy. We relied on their expertise to produce a bag of product to meet the specifications. These are licensed pharmacists, essentially, who oversee the production of these products: admixing and transferring the appropriate amount of product into the bag, and labelling it accordingly.

M^{me} France Gélinas: Now we know that the label did not accurately describe the contents of the bag, using your words. I take it that Medbuy knows that every time there's a hand-off, there is a risk for error. In health care, it happens everywhere—in pharmacy certainly, but also every other aspect of health care. Every time there is a hand-off, there is a risk for error.

In this particular case, going from preparing those mixtures in-house, patient-specific, to a hand-off to Medbuy, a hand-off to Marchese, a hand-off from Marchese back to the hospital: We've just added three layers of hand-offs; three layers of risk. How do you manage that risk? By the simple fact that you exist, you multiply the amount of hand-offs.

Mr. Michael Blanchard: We manage the risk by facilitating—our function is, we don't handle the product; we don't manufacture or admix the product. We essentially review with our members what are the practices, the standards, that are required for a pharmacy or to hand off a product, as you mentioned, to outsource the production. There are standards that these facilities employ to minimize that risk. Our job was to ensure that Marchese essentially met—or they stated they met all these criteria.

M^{me} France Gélinas: So you leave it back to your members or the hospitals to check?

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Mr. Michael Blanchard: We essentially—the committee, members and Medbuy staff—approached Marchese. There was a very comprehensive RFP process to evaluate the proponents—whether or not they had the standards and the facilities to produce a product within the guidelines, within the acceptable standards in the community. We felt that our comprehensive review provided us with sufficient comfort that they were capable of producing a product that was appropriately labeled and accurately prepared. The hospitals relied on that labelling, that it accurately represented the content of the bag. If it did, then we wouldn't be here today.

M^{me} France Gélinas: Other pharmacists have testified before you that it's not uncommon, when you mix a drug in a pre-set bag of saline, that you don't end up with the exact concentration; you end up with a little bit less because you add it into a bag of saline. This is not news to you, I take it?

Mr. Michael Blanchard: The commercially available pre-filled bags—there is overfill in them, and that's common knowledge. A qualified pharmacist would take account for that overfill in the preparation of their products. The label, again, would reflect accurately whether or not they did take that into account.

M^{me} France Gélinas: So you're telling us that the pharmacists at Marchese missed something that was obvious?

Mr. Michael Blanchard: I can't comment on what speculation—

Mr. Kent Nicholson: I think we can comment—back to my opening comments—that the specification, as it existed in the 2008 contract with Baxter, is identical to the specification that we went out to RFP for in 2011. So, Baxter had no issues understanding the specification and understanding that exactness was necessary in the handling and administration of chemo drugs. Their label indicated an exact concentration, and there was an exact concentration in the bag. So, our expectation was the specification was clear, that a licensed pharmacist would understand the necessity for exactness of these particular products, and that the label on the finished product was an absolute, accurate representation—four milligrams in 200 millilitres, not in approximately 200 millilitres, not in the total bag's contents. It's an exact definition: Four grams in 200 millilitres is an exact expression of concentration, not an approximation.

Mr. Michael Blanchard: And if I may add, qualified pharmacists would take that into account—the overfill—in their formulation. We spec'd out exact concentrations—one gram in exactly 100 millilitres. Qualified pharmacists would take that into consideration in preparing their product. They label it as an accurate, specific concentration in that bag, and if there wasn't, they should have adjusted the label accordingly.

M^{me} France Gélinas: Who should have caught that and adjusted the label accordingly?

Mr. Michael Blanchard: Well, Marchese, the pharmacist responsible for the production of the—

M^{me} France Gélinas: —the drug that Marchese—did you know that Marchese was unregulated?

Mr. Michael Blanchard: The pharmacist, to our knowledge—when we reviewed the criteria for awarding, one of the mandatory criteria was to have licensed pharmacists overview and oversee and supervise the production. With Marchese, we did satisfy ourselves that they were licensed; they had had licensed pharmacists in the province of Ontario. Regulated: We are aware of the regulation, that this is an area where oversight was a grey zone in terms of who was going to provide oversight for this type of production. Yes, we were aware.

M^{me} France Gélinas: You were aware.

The Chair (Mr. Ernie Hardeman): That concludes your time. Thank you very much.

We will now go to Helena Jaczek.

Ms. Helena Jaczek: Thank you for coming today and for providing us with exhaustive documentation.

Like my colleague, I just want to concentrate on a few issues that your presentation today did—it gave rise to a few questions, from my point of view. On your first page, number 5, you talk about your members and “expert member committees” who are “actively engaged ... in all aspects of our sourcing initiatives.”

Now, as I understand it, Medbuy is made up of members who are all from accredited health facilities, essentially—public hospitals and so on. So the individuals who are on your expert member committees are all individuals who have a job with a health facility and they have a specific expertise that could be valuable to Medbuy. Is that correct?

Mr. Kent Nicholson: Correct.

Ms. Helena Jaczek: Specifically, when it comes to pharmacy, could you describe who and how many people are on your pharmacy expert committee?

Mr. Kent Nicholson: Sure. I'll talk about the committee structure in general and then specific to pharmacies. We operate four portfolios. Those portfolios include operating room, materials management, medical imaging and pharmacy. Typically, every one of our member hospitals has a participant in each of those four portfolio committees.

Specifically to pharmacy, our pharmacy portfolio committee is represented by about 25 hospital members; it is often the director of pharmacy or a designate within their facility, so it's really a wealth of experience. Around our pharmacy table we have some recognized experts in the art of pharmacy. We lead that group also with licensed pharmacists who are employees of Medbuy.

So we do work very collaboratively with our membership, and our intention is to leverage the expertise that exists in our member hospitals to ensure if there's any unique requirements of their facility that their participating members are around the table to act as a voice for their particular facility.

Ms. Helena Jaczek: And these individuals do attend various facilities, various premises, where pharmacy preparation takes place, where compounding might take place. These would be the same people who would attend?

Mr. Kent Nicholson: Yes. We would typically not bring the entire committee. So in the instance that we described, at the outset when we posted our RFP and we were actually posting a sole-source validation, our intention was to renew the contract with Baxter. We didn't expect anybody would put their hand up, but in fact someone did put their hand up. So there was a visit. That particular visit was simply our staff, but our staff are also—we have the benefit of having licensed pharmacists as well.

We also reference in the document that in November 2012, we visited the Marchese Mississauga facility, again, as part of our normal course of in-contract vendor management that we would visit a facility. We visited that facility with representatives from our pharmacy committee—not the entire 25, but there were perhaps six or eight of our member hospital pharmacy directors, along with staff. We had a visit, and you'll find in the tab, post the visit, that Marchese, again, reinforced their capabilities and made reference to the fact that there's licensed pharmacist oversight. They even continued with a representation that they were an accredited pharmacy.

Ms. Helena Jaczek: So that type of inspection or visit does not include taking a sample of the product and testing it for validity—that the label is correct and that the concentration in the drug is there?

Mr. Kent Nicholson: It does not. Again, our expectation of a licensed pharmacist is when a label is stated as an exact concentration, that that is in fact the contents of the bag. That was our experience with the previous incumbent supplier for the five years that that particular contract was in place.

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Ms. Helena Jaczek: Well, it strikes me that that sort of visit is more of a paper chase. It's more just looking at the papers: “Is this an accredited pharmacy? Do they use sterile technique?” or a few things like that. There's no actual validation or objective assessment.

Mr. Michael Blanchard: No, there's no manufacturing validation of the drug content.

Ms. Helena Jaczek: Since we know that Marchese, apparently, was also contracted—as you have in tab 3A and 3B—for many other products: In light of what occurred and what you first learned of on March 22, what assurances do we have that these other products are at the correct concentration?

Mr. Michael Blanchard: Again, we rely on the quality and the skill set of a pharmacist to make sure that the drugs are reconstituted. You have to remember, the active ingredients are all approved from various vendors. They are approved by Health Canada. This is essentially the act of preparing a drug as prescribed by the directions from the various manufacturers and vendors. We have confidence that the non-oncology products are being transferred to the bags.

Ms. Helena Jaczek: Would you have any expectation that the hospital pharmacist would do any validation?

Mr. Michael Blanchard: No.

Ms. Helena Jaczek: Coming to your point 14: When you're assessing the various proponents' bids, you look at the pharmaceutical and label scores, and each can reach 30 points. I would assume, as a physician, that the labelling piece should be a no-brainer: You ask for a certain concentration and you stick it on the label. Am I missing something?

Mr. Michael Blanchard: You are correct.

Ms. Helena Jaczek: In terms of the pharmaceutical piece, could you describe a little bit more how a proponent might gather those 30 points?

Mr. Michael Blanchard: If you refer to—I believe it's tab 1A. Just to give you an example: In tab 1, A and B, essentially, are the criteria that the proponents—the vendors that responded to the bid. If you take a look at pharmaceuticals, for pharmaceuticals there are several criteria that address the quality: the qualifications of the staff, the environment, the production facility. Do they meet certain standards? Are there clean rooms? Do they have certification of the clean hoods that they're utilizing in preparing the production? Identifying the training of their staff, the recertification of their staff etc.

Ms. Helena Jaczek: So you look for the certification or the training, that these individuals have obtained this particular piece of accreditation? You look at the facility to see that there are fume hoods or there are negative-pressure rooms? You physically do look at that piece?

Mr. Michael Blanchard: When they visited—basically, when you're looking at these—yes, we do look at them.

Ms. Helena Jaczek: Yes. Okay. Well, that's reassuring.

For those 30 points on the pharmaceutical side, I guess I'm a little surprised that it wouldn't be an all-or-nothing. Before you look at finances, before you look at business scores, I would have thought that when you are trying to obtain a pharmaceutical product, it's so important to have that absolutely correct that there has to be at least some minimum that would be acceptable out of the 30. Frankly, I would have thought you'd want to see 30 every time, before you looked at the other two scores. Is it a stepwise type of process in terms of looking at the proponents bidding on the RFP, or is it a combined score?

Mr. Michael Blanchard: There is a mandatory, and in this case the mandatory was that they needed a licensed pharmacist. That was the mandatory, and once they qualified and met that mandatory requirement, then the other criteria—it would be a combined score, the best score of the remaining.

Mr. Kent Nicholson: It is not unusual for us—again, I don't have the information directly in front of us, but it's not unusual for us to have, for the area of clinical—and in the pharmacy world, it would be called pharmaceutical—a minimum score, that if somebody doesn't meet that minimum score, their bid is rejected. It's not unusual for us to run initiatives that do have a minimum

clinical score to have you continue to be a qualified proponent.

Ms. Helena Jaczek: Okay. Now, obviously, your contract was signed with Marchese Health Care, which you were satisfied was accredited, licensed pharmacist etc. But you knew that the facility you visited was not currently compounding chemicals. When you started to see Marchese Hospital Solutions coming back on various documentation and so on, did that raise any further questions about was this a licensed, accredited facility?

Mr. Michael Blanchard: My recollection of some of the readings of the documents—there's evidence to support that the initial production did occur in a facility other than the Mississauga facility. They did inform us—they had demonstrated or introduced plans to us to move the production to a new facility, and they were awaiting accreditation from the college of pharmacy of Ontario. They did notify us in an email of the date that they had received accreditation and were moving the production for the hospital to that new facility. They also indicated at that time that they were introducing a new business name, Hospital Solutions, to clearly distinguish between their hospital division and their retail home care division.

Ms. Helena Jaczek: Am I understanding that the feeling at Medbuy was that, notwithstanding this name change—Marchese Hospital Solutions—it was an accredited facility by Health Canada?

Mr. Michael Blanchard: Not by Health Canada. It was an accredited facility. It was a licensed pharmacy—

Ms. Helena Jaczek: But it was a pharmacy.

Mr. Michael Blanchard: A pharmacy accredited by the Ontario College of Pharmacists.

Ms. Helena Jaczek: If you had known that it in fact fell into this grey zone and was not accredited by the College of Pharmacists, in that the College of Pharmacists cannot enter that premise—at least to date; we hope they will be able to, but not at this moment in time—would you have continued with the contract?

Mr. Kent Nicholson: At that point in time—and again, represented by what we deemed to be the mandatory requirement. The mandatory requirement that we specified was that the work needed to be supervised by a licensed pharmacist. If we had put in a requirement as mandatory that you also had to be an accredited pharmacy, the previous incumbent, Baxter, would not have qualified. They were not, and still are not, to our knowledge, an accredited pharmacy. It was not part of the scoring, it was not part of the consideration. They made a representation that they were an accredited pharmacy, but what was a mandatory requirement for us was that the work was supervised by a licensed pharmacist.

Ms. Helena Jaczek: So you really were not aware that there was this grey zone, as we've heard it described. Or you just felt if there was a pharmacist there who was accredited, licensed by the College of Pharmacists, that was enough.

Mr. Michael Blanchard: I refer you back to our opening statement. This is a practice hospitals outsourced to a third party for nearly three decades. We had at the

time I believe 14 hospitals with individual arrangements with Baxter, essentially. In order to attempt to streamline—it was an effort to consolidate these individual hospital agreements to one agreement, and that was sort of the motivation for the 2008 contract with Baxter. This was an acceptable practice in the community. Health Canada and the College of Pharmacists were well aware of this practice, and it's a practice that has been ongoing for—like I mentioned before, I think Baxter has been in business for nearly 27 years.

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Ms. Helena Jaczek: Obviously, in light of this incident, the Ministry of Health and Long-Term Care has become very involved. They've established a working group. Are you part of that working group?

Mr. Michael Blanchard: No, I'm not.

Ms. Helena Jaczek: Is Medbuy at all involved?

Mr. Kent Nicholson: We're not. We've been approached, obviously, by Dr. Thiessen, and we've been approached by the Ministry of Health. We have shared much of what we've shared today. Contract detail, specification detail: All of that has been shared. To date, we've not been asked to participate in a working committee, if that's the term that you used.

Ms. Helena Jaczek: Then have you heard about the potential of some regulatory oversight by the College of Pharmacists? Do you feel that this is a good idea?

Mr. Michael Blanchard: Yes, it is.

Ms. Helena Jaczek: So this little gap that you've known about for some time will be addressed by the regulation?

Mr. Michael Blanchard: Again, it doesn't mean that the standards are going to change. The proponents are stating that they're compliant with these standards that are published in the community: USP 797, for example, which is the gold standard for admixing.

What this will do is bring forth an oversight body that will ensure that these vendors, service providers, are working to that standard.

Ms. Helena Jaczek: How much time, Mr. Chair?

The Chair (Mr. Ernie Hardeman): You have about two minutes left.

Ms. Helena Jaczek: Okay, we'll save that.

The Chair (Mr. Ernie Hardeman): Okay. Ms. Elliott?

Mrs. Christine Elliott: Thank you, Mr. Chair. Thank you very much for joining us this afternoon and for answering our questions. Some of my questions—I'll hope you'll bear with me. I haven't had a chance to go through all of the documents in detail.

I would like to go back, if I might, to 2008, when you first decided to issue an RFP for admixing services. I recognize that probably neither of you was involved in that, but do you have any knowledge about what process was gone through in order to establish the basic standards in order to develop the RFP in the first place?

Mr. Kent Nicholson: I'll start off, and Michael may be able to contribute as well.

We've done a lot of source-document-looking and investigation to try to understand the history of our involvement. Our pharmacy committee actually first raised this as a potential contracting opportunity for Medbuy in 2005. It came up in 2005 at a pharmacy committee that Medbuy should undertake to evaluate going to market for this particular service, which, again, was driven by the fact that many of our member hospitals, even at that point, were already using a third party compounder.

When we finally did make the decision in 2008 to put it on an RFP—it was a large RFP. This was a component of a larger RFP. In the same way that we create specifications for everything we go to market on, we would engage our pharmacy committee as experts. In this particular instance, our pharmacy committee had direct experience in contracting for a compounding service. We, in collaboration with them, would have created the first specification that we took out to market in 2008.

Mrs. Christine Elliott: And the contract ultimately went to Baxter. Was the same RFP used in the second, in 2011, or was it—

Mr. Kent Nicholson: Same specifications. Again, we've included it in the documents. There is a tab that simply lists the products that were on the previous Baxter contract as well as the products that went into the RFP. These particular chemo drugs are described the same way.

Mr. Michael Blanchard: It would be tabs 6A and B.

Mrs. Christine Elliott: One of the issues that has arisen here is the issue of concentration-specific solutions versus non-concentration-specific. It appears that you had always intended the contract to be for concentration-specific solutions. Did you have any discussions, first of all, with Baxter about that? And secondly, with Marchese on the same issue?

Mr. Michael Blanchard: I can't recall seeing any evidence or documentation. I think Baxter prepared the product according to the specifications on the label, and I have no knowledge of any problems with Baxter products.

Mrs. Christine Elliott: So Baxter always complied with your requirement—

Mr. Michael Blanchard: To our knowledge.

Mrs. Christine Elliott:—for a concentration-specific solution.

Mr. Michael Blanchard: Yes, to our knowledge.

Mrs. Christine Elliott: In just taking a brief look at the contract, I see that you're contracting for sterile preparation compounding services, but it doesn't specifically state in the contract, at least in my reading, that you want concentration-specific solutions. Now, I see that there are drugs that are listed and there are concentration-specific solutions listed there, I believe, but is there anywhere in the contract that it specifically states that's what you're looking for?

Mr. Michael Blanchard: We—and again I'm not that familiar with all the terms in the contract, but certainly we would refer the proponents to the one of the schedules, which would be the list of products. On this list of

products, there's a drug name, a drug strength, in a specific volume. Then there's also labelling criteria, which I believe are in one of the tabs, that basically state, "This is what your labels will be scored against." Again, there is a specific requirement in that list of criteria; I believe there are 12 or 14 criteria. But one of them does specifically state concentration—you know, a certain strength of the drug, in a certain specific volume. That whole package is posted electronically, and it's all part of the information that is provided to the proponent.

Mrs. Christine Elliott: So really, it was the specific concentration you were looking for, and however they arrived at that, your expectation was that the concentration stated on the bag was exactly correct.

Mr. Michael Blanchard: Correct. There are no assumptions otherwise. I mean, a professional qualified pharmacist would ensure that. If that was not the case, they would have not labelled it that way.

Mrs. Christine Elliott: Was there ever any discussion about the means of preparing the solutions? I understand that there are many different ways that one can do that, from just withdrawing some of the solution, mixing it with the powdered medication and then adding it back, which would account for a non-specific solution, versus specifically filling an empty bag, for example.

Did you have any discussion with Marchese about the process that they used in order to complete these solutions and fill them?

Mr. Michael Blanchard: My understanding is that it was part of engaging a qualified pharmacist. There are many ways of addressing—you know, there might be two or three different methodologies to prepare a product, and it's up to the individual professional pharmacist to make that determination. But the end point is specific: The content of the bag should reflect accurately what is stated on the label.

Mrs. Christine Elliott: As you may know, the president of Marchese testified before the committee last week, and she indicated that what she contracted for with Medbuy was for non-specific concentration solutions. Do you have any idea where she would have gotten that notion?

Mr. Michael Blanchard: I don't know. I couldn't—you know, from all the documents I read and in my conversations with the staff, there doesn't seem to be any indication that we would have suggested that.

Mrs. Christine Elliott: But is it fair to say that Marchese did not prepare the product that you were expecting?

Mr. Michael Blanchard: That is a fair statement.

Mrs. Christine Elliott: Thank you.

The Chair (Mr. Ernie Hardeman): Mr. Yurek?

Mr. Jeff Yurek: Thank you. Just going back to Medbuy: Who oversees Medbuy, how it operates? Who's the overseer of Medbuy? Or do you have one?

Mr. Kent Nicholson: Well, we have a governance model, so we have a board of directors that provides oversight to management, obviously. In terms of what we need to be compliant to: certainly the Broader Public

Sector Accountability Act. We can be audited at any point in time.

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Mr. Jeff Yurek: Have you ever been audited?

Mr. Kent Nicholson: Not a full-blown audit, to my knowledge, but certainly we get inquiries from time to time. Typically it's from unsuccessful proponents who want to take issue with our process, so we get a number of issues that are very initiative-specific in terms of us having to defend—we provide some detailed documentation similar to this in terms of how we do scoring and how we publish criteria. Any proponent that replies to an RFP of ours does get to see the scoring criteria as part of the RFP that we put out, so we tell them the weighting and the scoring criteria and how each of the sections will be scored. We do face challenges periodically where the BPS secretariat will inquire about a specific initiative, and we'll provide documentation that supports that we took it out in a fair and transparent and compliant way.

Mr. Jeff Yurek: Has the Ministry of Health ever been involved in giving you any guidelines specifically on how to procure compounded medications or any types of medications, per se?

Mr. Kent Nicholson: Not to my knowledge.

Mr. Jeff Yurek: So you've never had any discussion with the Ministry of Health. How about the LHIN? Did the LHIN ever talk to you about procurement of any sort?

Mr. Kent Nicholson: We have had meetings with LHIN representatives, more from building an awareness of the work that we do. Again, as people come to understand the work that we do the way that we've described it today, I think it's reasonably self-evident how we operate. Those inquiries don't tend to come at us in terms of trying to give us advice around how to run a public procurement, but more in a spirit of understanding what we do and how we add value to the system.

Mr. Jeff Yurek: Do you think it would be helpful if the Ministry of Health was involved with these types of product procurements, giving you at least some standards to meet?

Mr. Kent Nicholson: Back to the conversation around a gap in oversight: I can't think of anything bad that would come from further oversight in this area. I think it has been recognized—and you've probably had a number of people come to the standing committee and speak about the fact that manufacturers are highly regulated—that pharmacies are highly regulated and that this particular service falls somewhere in the middle. I can't think of anything bad that would come from further oversight, inspections and standards. I think that we would welcome that, and I think the people who are in this particular line of business would welcome that kind of oversight.

Mr. Jeff Yurek: Earlier you testified that one of the hospitals was unhappy with the labels. Do you have a mechanism in place where the hospital can say, "I'm not happy with this product"? What do you do with regard to that? Perhaps you can table some documentation showing how you've dealt with an issue like that before.

Mr. Kent Nicholson: Sure. There are processes whereby a member hospital could exclude themselves from an initiative, either at the outset of the initiative or at any point in the contract. There's very specific language that says that if you believe that there's any negative impact to patient care, patient safety or employee safety—those kinds of considerations—you can, at any point in time, advise us and we'll evaluate that. If, in fact, we agree, then you're released from your commitment from the contract.

Mr. Jeff Yurek: What if you didn't agree?

Mr. Michael Blanchard: Just to add to that, we also do have efficient tracking processes in place. Where members have a concern with the product, they can use our website to report or email us. There is a process and staff dedicated to monitoring and managing product concerns and follow-up with the vendors to modify—it could be a label, shipping; any of these issues. If it's a quality issue, it becomes a priority. If the vendor or the producer or the supplier cannot modify or rectify the problem, then we take the necessary action to sever the agreement.

Mr. Jeff Yurek: What if the hospital called in and said, "We're not happy with this product"? You review it and you say, "Well, we don't agree with you, but"—

Mr. Kent Nicholson: To my knowledge, we've never done that. We don't put ourselves in the place of the clinician. If a member hospital comes to us with a well-thought-out rationale as to why this does not meet their needs or does not meet the needs of their patients or the demographics—to my knowledge, we have never not accepted a member being excluded.

Mr. Jeff Yurek: I'm just going to go back to the contract. I haven't had a chance to—it's on my desk. You were just briefly going through the contract here. On the list of meds here, you can't really tell what you would use as a single and what you would use as a concentration-specific bag. It's just not glaring at me right here that a supplier or manufacturer or compounder or whatever wouldn't—it's not spelled out to them that this bag is going to be used multi-use or this bag is going to be a one-time use.

Mr. Michael Blanchard: Again, the reason for having all of the products listed—the requirement is to have an expression of concentration on the label. The end user, the pharmacist or the nurse, can then determine if there is a dose adjustment required. For example, in oncology, several patients—as I mentioned earlier, dosing is patient-specific. So a pharmacist would then, if they wanted to use "a bag" as a stock bag, and if it's labelled as we required—our requirement, our specification, was that it be a specific concentration on the label; that the bag contains a specific amount of product.

Mr. Jeff Yurek: Is that spelled out in the contract?

Mr. Michael Blanchard: It's spelled out, as I mentioned, to Ms.—

Mr. Jeff Yurek: Ms. Elliott?

Mr. Michael Blanchard: Christine Elliott. Ms. Elliott.

One of the schedules of the contract is the list of drugs that we provided to you—

Mr. Jeff Yurek: But it doesn't say "concentration-specific," though.

Mr. Michael Blanchard: Well, it does. If you take a look: cyclophosphamide, two grams in 100 millilitres. That's concentration-specific.

Mr. Jeff Yurek: That would be—what?—20 milligrams per millilitre, would be the concentration.

Mr. Michael Blanchard: Correct.

Mr. Jeff Yurek: So that holds true for the cefazolin? Would you expect two grams in exactly 50 millilitres?

Mr. Michael Blanchard: Yes.

Mr. Jeff Yurek: With cefazolin, you get the whole bag anyway. Is it assumed that that's fine—

Mr. Michael Blanchard: Well, it is not as clinically sensitive, but our specs did require that.

Mr. Jeff Yurek: Is that written in here that that's what you're—

Mr. Michael Blanchard: The specifications for each product are listed in the schedule, which we indicated here in tab 6A and B. So 6A is the list for 2008. These lists are part and parcel of the contract. It includes the contract.

Mr. Jeff Yurek: This is 2008?

Mr. Michael Blanchard: So 6A is 2008, which was awarded to Baxter, and 6B are the specs that we went out to market with for the 2011 RFP. So it is essentially two grams in 100 millilitres of sodium chloride per bag.

Mr. Jeff Yurek: Was this spelled out to Baxter and the other two proponents when they bid on it?

Mr. Michael Blanchard: Yes.

Mr. Jeff Yurek: It was spelled out specifically—

Mr. Michael Blanchard: Yes.

Mr. Jeff Yurek: —that cefazolin is going to be two grams, and I expect it in 50 millilitres?

Mr. Michael Blanchard: Yes.

Mr. Jeff Yurek: Okay.

The Chair (Mr. Ernie Hardeman): Ms. McKenna?

Mrs. Jane McKenna: When we had Ms. Zaffiro in here, she had said that she felt that the communication had broken down, and the relationship was with yourselves, because the contract was between you and her. Her number one thing that she had already said was that her understanding was that it was one full bag per person and that it was non-specific-concentrated. So where would she get that information from?

Mr. Michael Blanchard: I have no indication, in the documents that I've read at Medbuy and the conversation I've had with the staff, that we would have suggested that to her. We have evidence. It's surprising, since the doses of gemcitabine and cyclophosphamide that were in the two bags in question were significantly higher than what could be used on one patient, and any qualified pharmacist would know this.

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Mrs. Jane McKenna: If it was clear as ice, it wouldn't be taking a year for one person or three people to actually find the mistake in the first place. There seems

to be a lot of overlap or miscommunication somewhere along the board here, because it's confusing just sitting here. It seems to be that your specific of what you're saying is that it's as clear as ice, but clearly it wasn't, because Marchese was in here and she had clearly said that—she was very stern on the fact that it was one bag per person that she understood and that it was non-specific-concentrated. So somewhere in the contract or somewhere there was miscommunication somewhere. Do you feel that there was that?

Mr. Kent Nicholson: I actually don't. We've spent some time thinking about how we could be clearer. The specification of the product, in our mind, is very clear. The labels that Marchese placed on the bag are also very clear. Both are an exact expression of concentration. For it later to be viewed that these bags were not supposed to be concentration-specific—quite frankly I don't understand.

The other thing I don't understand is: In the case of four grams of gemcitabine, that would be a harmful dose to a single patient. So to make an assertion that there was a belief that the patient was going to receive the entire bag—that would be a harmful dose.

Mrs. Jane McKenna: Okay. I have one other question. We had London Health Sciences Centre in here, and Sandy Jansen, who was the director of pharmacy services, said that when they received the label in the RFP process, it was different when they actually received the product. So what was the difference?

Mr. Kent Nicholson: One of the differences—and again, the labels are included in the package, both sets of labels.

Mrs. Jane McKenna: Yes.

Mr. Kent Nicholson: So one of the differences clearly is the introduction of Marchese Health Solutions, or—excuse me—Marchese Hospital Solutions. At no point did we ever request that the label be changed. There was a change to the label. The most glaring change is, it used to be Marchese Health Care. It's now Marchese Hospital Solutions. When that change was made, there was also apparently some cleanup. So if you compare the two sets of labels, there was an attempt to make the concentration stand out more in the Hospital Solutions instance. The exact concentration is actually identified in a box. Some redundancy was taken off the label. The label would appear to have gone through some changes in a spirit of making it actually clearer and more specific in terms of the concentration, not the reverse.

The Chair (Mr. Ernie Hardeman): That concludes your time. We have two minutes left on the Liberal side. Ms. Jaczek.

Ms. Helena Jaczek: Yes. Thank you. Just to go back to the fact that you were reassured that Marchese Health Care was a pharmacy licensed by the Ontario College of Pharmacists, which enabled it to provide infusion services etc.: Definition of a pharmacy—it strikes me that how we normally think of pharmacies is, there's a prescription, there's a patient's name, there's a dose. Do pharmacies, currently licensed, make up stockpile solu-

tions of certain concentrations from which they can draw as needed when the patient-specific prescription comes in, or do they make it up de novo per patient in a pharmacy?

Mr. Michael Blanchard: The latter statement is probably practised in a retail setting.

Ms. Helena Jaczek: So then, what I would say is: What comfort did you derive from this, knowing that this was a stockpile, a concentration, as you felt it should be, to be delivered to hospitals for multiple use?

Mr. Michael Blanchard: They're batching for several patients, is what you're trying to say.

Ms. Helena Jaczek: Right, but you derived comfort from the fact that this was a pharmacy?

Mr. Michael Blanchard: A pharmacy—the mandatory was the supervision of production by a licensed pharmacist.

Ms. Helena Jaczek: Even though it wasn't going to be patient-specific. It was clearly compounding for many patients, from your perspective. Is there some way—I guess we're trying to speculate how—Marchese misunderstood the fact that this batch would be used for one patient? Could it relate to the fact that—

Mr. Michael Blanchard: This is something that the pharmacists—if I may?

The Chair (Mr. Ernie Hardeman): You go ahead and finish answering.

Mr. Michael Blanchard: Okay; thank you. I was just simply going to state that Marchese has been in the business of servicing home care patients, and they would probably, I would think, prepare their production in batches also.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time. We thank you very much for coming in this afternoon and sharing your information with us.

Mr. Michael Blanchard: You're welcome. Thank you.

ONTARIO COLLEGE OF PHARMACISTS

The Chair (Mr. Ernie Hardeman): As you're packing up, the next delegation is the Ontario College of Pharmacists.

Interjections.

The Chair (Mr. Ernie Hardeman): If those wanting to do the scrums would please go outside the doors to do them.

Interjections.

Ms. Helena Jaczek: That's a novel approach.

The Chair (Mr. Ernie Hardeman): I can only speak so loud; I can whistle louder.

Okay. We'll get back to order in the court. As I said, our next delegation is the Ontario College of Pharmacists: Marshall Moleschi?

Mr. Marshall Moleschi: Yes.

The Chair (Mr. Ernie Hardeman): I think you were here at our previous meeting and you were sworn in, so with that, you will not have to go through that process

again. As we did that day, you will have 20 minutes to make a presentation, and then we will have—what shall we say?—an around-the-room for questions for 20 minutes each. This time, we'll start with the government caucus.

With that, Marshall, the floor is yours.

Mr. Marshall Moleschi: Thank you very much. I'd like to take this time to just remind the committee of the role and the mandate of the college, to recap some key information that was initially presented to this committee when I was before you on April 16, and give you an overview of some of the activities that the college has been involved in that have transpired since that time. Throughout my remarks, I'll give additional insight and clarity to some particular issues, and I'd be glad to answer your questions.

The Ontario College of Pharmacists is the regulatory body for the profession of pharmacy in Ontario. The college receives its authority through a variety of laws, including the Pharmacy Act, the Regulated Health Professions Act, which is the RHPA, and the Drug and Pharmacies Regulation Act, which is in short the DPRA. The specific objects of the college are set out in the health professions procedural code. In carrying out these objectives, the college's duty is to serve and protect the public interest.

To be a pharmacist or a pharmacy technician in Ontario, you need to be registered with the college. To operate a community pharmacy in Ontario, you need to be accredited by the college. Section 118 of the DPRA specifies that the college does not have jurisdiction over "drugs compounded, dispensed or supplied in and by a hospital," so there is an exemption there.

The activities of the college are subject to a number of oversight mechanisms, including both general and specific oversight by the Ministry of Health and Long-Term Care and specific oversight by the Health Professions Appeal and Review Board and the Health Professions Regulatory Advisory Council. As required by the Pharmacy Act, the college is overseen by a council of 17 pharmacists elected from the electoral districts of the province, two of whom are in hospital practice; two elected pharmacy technicians, one from a hospital practice; 16 public members appointed by the Lieutenant Governor in Council; and finally, the deans of the University of Toronto and University of Waterloo are also on council.

With respect to practitioners, the college has regulatory oversight for the competence and conduct of pharmacists and pharmacy technicians, regardless of where they practise, as outlined in the RHPA.

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The college is responsible for setting and maintaining entry-to-practice standards to ensure that practitioners have the knowledge and skills necessary to safely and effectively practise pharmacy when entering the profession.

Once in the profession, pharmacists and pharmacy technicians must adhere to the college's quality assurance

program, which requires practitioners, on a regular basis, to demonstrate their ongoing competence throughout their careers. We hold practitioners accountable to practise within their scope of practice and in compliance with all relevant regulations, standards of practice and ethical conduct.

The college's authority over the place of practice is outlined in the DPRA and, as already mentioned, is currently restricted to community pharmacies. And that section 118 excludes jurisdiction over the hospital. The accreditation process for community pharmacies includes: the college setting and maintaining accreditation standards, inspecting pharmacies before they open and soon after opening to ensure they meet these standards, and conducting routine inspections approximately every three to five years, but if it's warranted, much more often than that.

Should there be a concern raised regarding an accredited pharmacy or an individual pharmacist or pharmacy technician, we have a complaints, inquiry and discipline process whereby any member of the public can file a written complaint with the college, or, as registrar, I can initiate an investigation into any relevant matter. All complaints are investigated in a timely way. Priorities are based on risk of harm to the public, and notice and findings of discipline cases are made public.

Public trust and confidence is maintained through our public register, which lists all pharmacists and pharmacy technicians currently in good standing, with notations regarding any disciplinary action that they may have. The college website also provides a list of all community pharmacies in good standing. As reported in the college's most recent annual report, as of December 31, 2012, there were 13,400 pharmacists and 1,023 pharmacy technicians registered with the college and 3,567 accredited community pharmacies.

During my April 16 testimony, my initial session before this committee, the focus of my opening remarks and your subsequent questions was specifically to the college's understanding and actions pertaining to the incident of chemotherapy under-dosing. During that testimony, I provided a chronology of the events that transpired since first learning of the incident on March 31. I reported that our initial focus was on ensuring that appropriate steps were in place to ensure public safety and to address patient concerns.

On April 3, the college, utilizing its authority under section 75(2) of the health professionals procedural code, appointed an investigator to look into the competence and professional conduct of identified members. On that day, together with two Health Canada inspectors, the college investigator visited the accredited pharmacy, Marchese Health Care pharmacy, and was given permission to visit Marchese Hospital Solutions.

On April 4, the college, with Health Canada, reviewed the respective memos of the joint visit to the premises from the day before and developed next steps, which included the development of specific questions for the identified members.

On April 8, having confirmed the distinction between Marchese Health Care pharmacy, which is the accredited facility by us, and Marchese Hospital Solutions, which was a federally incorporated company contracted to produce the medications in question, the college publicly acknowledged that Marchese Hospital Solutions was not an accredited pharmacy and was outside of our regulatory authority and our inspection process.

The college's investigation then proceeded into the specific situation, and this investigation is ongoing and could take a few more months to complete the whole process. The focus is on the member and the possible misconduct of the member. Once completed, the findings from the investigation will, as per the college's procedures, be referred to the college's constituted committee for disposition. The outcome could be a possibility of three things: a referral to discipline, something that could be in the neighbourhood of a caution or it could be determined that there's no further action that needs to take place. All matters referred to discipline are made public.

Also, in our initial session on April 16, I advised this committee that the college was an active member of the ministry's working group, providing support to Dr. Jake Thiessen's independent review of quality assurance in the province's cancer drug supply chain. Finally, I reported that we were working diligently with the ministry to identify opportunities to make enhancements to our jurisdiction to provide authority into the oversight of facilities that fall in these identified grey areas.

Since April 16, the college has been engaged in a significant amount of activity regarding this situation. Already mentioned, our work on the specific investigation relating to the activities of the identified individuals at Marchese Hospital Solutions is ongoing.

At this time, it might be helpful for this committee if I were to take a few moments to outline the college's process, which, of course, is outlined in legislation with respect to how the college conducts investigations.

In cases such as this, the process begins when I, as the registrar, become aware of a situation where there are reasonable and probable grounds to believe that a member may be incompetent or has committed an act or acts of professional misconduct. I then can appoint an investigator to essentially initiate an investigation by inquiring into and examining the practice of identified members. This is what happened on April 3.

During the course of an investigation, there may be a number of site visits conducted, ongoing interviews and dialogue, gathering of relevant materials and a comprehensive review of the policies and procedures. As of today, the college remains in this stage of the investigation.

Once the investigator is confident that they have gathered all the relevant information, a report of their findings is forwarded to the college's inquiries, complaints and reports committee—we call that ICRC—as well as to any member named in the investigation. It is currently anticipated that the report of this investigation will be completed toward the end of May.

Once the report is received, the member has 30 days to provide the ICRC with any written submissions they may have. This would bring us to the end of June. The ICRC will then review the report at their next scheduled meeting and provide their disposition, which will be one of three things: referral to discipline, something like a caution to a member, or require no further action be taken.

Given the timeline that's outlined above, it's anticipated that the earliest this matter could be brought before the ICRC is in their July meeting. Should the ICRC refer the matter to discipline, it would mean that there are allegations of professional misconduct.

In addition to our own investigation, we are also actively participating in the working group of Dr. Thiessen's independent review. To this end, Dr. Thiessen has visited the college, reviewing and interviewing myself and Anne Resnick, the director of professional practice. This was done on April 23. During that session, the college shared with Dr. Thiessen a full chronology, which has also been shared with the ministry, of all correspondence between the college and Marchese Hospital Solutions and Marchese Health Care's pharmacy.

These include acknowledgement of initial contact with representatives from the Marchese group in late 2011 or early 2012 where they asked the college for clarification on regulatory requirements for a start-up business providing non-traditional pharmacy services. Upon request, Marchese provided the college with detailed descriptions of the proposed operation. The document describes a business that would prepare admixtures to fill bulk orders for hospitals. The business was not intended to deal with the public or fill orders pursuant to individual prescriptions.

As such, the college concluded that the proposed business would not be functioning as a pharmacy and may be considered manufacturing, and the college directed Marchese to contact Health Canada. Marchese indicated that they were going to do so.

The college's next contact with the Marchese group was when the accredited pharmacy, Marchese Health Care, received a routine inspection in January 2013. Although the outcome of the routine inspection was that Marchese Health Care met accreditation standards, the inspector did make a note of questions relating to the bulk hospital preparation business being conducted by Marchese Hospital Solutions, which was adjacent to the accredited pharmacy.

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Notes reflected that the designated manager of the accredited pharmacy indicated that Marchese Hospital Solutions was not regulated or inspected by Health Canada at this time, but was operating under the Public Hospitals Act. The college inspector further noted a few potential areas of overlap, and instructed the designated manager to ensure that the orders being filled by Marchese Hospital Solutions were filled separately from the Marchese Health Care pharmacy, and that the supervision of the accredited pharmacy should not be

compromised while they were attending to Hospital Solutions business.

In short, the college clearly communicated to the accredited pharmacy that there needed to be clear separation between themselves and the Hospital Solutions business, and requested that the college know the outcome of their interaction with Health Canada regarding acquiring an establishment licence for Marchese Hospital Solutions. There was no further dialogue between the college and Marchese until the incident in question.

With respect to our ongoing work with the ministry on the development of additional authority to oversee these facilities, on April 26 the college posted, for circulation, draft regulations and bylaw amendments. Understanding the importance and timeliness of this, the college made a request to the ministry for approval to abridge the circulation period, in accordance with subsection 95(1.6) of the health professions procedural code, from 60 days to 10 days. This was approved by the ministry. The draft regulation and bylaw amendments were posted on our website and have been available for comment since April 26. Given the 10-day requirement, they will close today at 5 p.m.

For clarification, I thought it might also be helpful to briefly summarize the proposed regulation and associated bylaws. These will provide the college with regulatory oversight over drug preparation premises where pharmacists and pharmacy technicians practise. Because of the language limitations of the legislation, the college's authority is provided under the Regulated Health Professions Act and the Pharmacy Act, not under the Drug and Pharmacies Regulation Act, which governs accredited pharmacies that provide pharmacy services directly to the public.

As per the regulations, any pharmacist or pharmacy technician engaged in or supervising drug preparation activities at or in connection with a drug preparation premises will be required to notify the college. These identified drug preparation premises will then be inspected by the college.

The proposed bylaw amendments further specify that the outcome and/or status of the inspection of these drug preparation premises will be posted on the college's public register.

Additionally, on this specific point, the college has brought forward separate proposed bylaw amendments that would establish a distinct public register of accredited pharmacies that would also include the posting of the outcome and/or status of their inspections, so it would be both the pharmacies and the drug preparation premises.

It's important to note that the combination of the college's proposed regulation and the ministry's proposed regulatory change to the Public Hospitals Act will ensure that hospitals only purchase from accredited or licensed suppliers. That will close the identified gap in the regulatory oversight.

Although the college's proposed regulations and bylaws outline some timelines relating to the college's

identification and inspection of these facilities, the college is working diligently to expedite these timelines. It is anticipated that the regulation would take effect in late August or early September, but we're working now on establishing all the necessary processes and inviting voluntary identification and, potentially, inspections prior to authority being received.

Although it's still not completely clear as to the number of drug preparation premises currently operating, information gathered by ourselves, the ministry, the Ontario Hospital Association and Health Canada is indicating that the number is going to be around half a dozen. Given this and the efforts made by the college in anticipation of receiving this new authority, we anticipate being able to inspect all of these facilities before the end of this year.

A special meeting of the college council has been called for this Friday, May 10. The final draft of the proposed regulations and bylaw amendments, which will reflect all the feedback that has been received during the circulation period, will be presented to council at that time for approval. Assuming that approval is given, the regulations will be forwarded to government for their consideration for filing. Should the government decide to file the regulation, it will take effect 90 days after the date of filing, which, as previously indicated, would bring us to late August, early September as a timeline for when the college's authority in this area would commence.

I hope these opening remarks have helped to provide you with a clearer understanding of the role and the mandate of the college, summarize our conversation from our initial meeting on April 16, and bring you up to date on the many activities that the college has, and continues to be engaged in, and provide some further insight and clarity along the way.

At this time, I'd be happy to answer any questions you may have.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. We will start the questions with Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair, and thank you, Mr. Moleschi. You've certainly had a very, very busy time since March 31. Not only were those first couple of weeks obviously very busy for you, but since you came on April 16, you've taken a number of actions.

In terms of the College of Pharmacists, with the new regulation and the bylaws, you've sort of given us a little bit about how you're trained to expedite this. You've shortened this consultation period, I believe—

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: What happens from here on in so that the bylaws will be in place?

Mr. Marshall Moleschi: So as of 5 p.m. this afternoon, the consultation on both the bylaws and the regulations will be concluded. We'll take the information that we receive from the feedback and we'll go back to our lawyers to see what can be incorporated and what makes sense and what is on target toward what we're

delivering. Then by Friday, we'll have those—both the regulations and the bylaws—in front of the council. Council will take the time it needs to ensure that that's meeting the intent that is there. If the council passes that, then they will be sent to government, and the ministry will then present it to government for filing.

During that period of time, there will have to be 90 days after that before it comes into effect. But at the same time, we haven't stopped our activities; we're very much involved in things. As a matter of fact, tonight, someone is arriving from another province where they're—they're doing not exactly what this is, but they do inspect hospitals. They do, in that province, have some central fill type of capability where they do some bulk packaging, and they do look at that. It's all within the health authority. But that expert will help us not only with the evidence that we've gathered but also with some procedures, what the standards are that we need to meet. We've received already a copy of their rough inspection form—well, it's not the rough form; it's what they use for an inspection form—and we'll ask all the questions. So throughout this week, he'll be working with us to be able to put some of these processes in place.

We're not inventing everything from scratch; we're putting something in place that has worked in a similar—not exactly the same—environment in another province so that we can take advantage of that.

Those documents, those standards, refer to Canadian national standards and international standards; I think USP 797 was mentioned and it refers to that. It also refers to regular compounding, sterile compounding and high-risk type of compounding, and there are different standards for those. We'll have to get a better understanding of what those references are, but we are using the work that other provinces have done to be able to build on that.

Ms. Helena Jaczek: Are you getting quite a bit of feedback on the proposed regulation? You say it's closing at 5 p.m. today.

Mr. Marshall Moleschi: I think after a couple days, there were like 3,000 hits on our website. There was dozens of feedback—there's a way that you can easily comment on the regulations, and there were dozens of them, although I'm not up to date as to what has transpired throughout the day today. There's a significant number.

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Ms. Helena Jaczek: So, obviously, it will take a certain amount of time to sift through all that and potentially incorporate suggestions into the final product for this bylaw.

Mr. Marshall Moleschi: It's going to take a lot of work to be able to do that, but we will not take a lot of time to do that. In other words, we'll work very diligently to be able to provide that, simply because we have the council meeting on Friday and we'll have to work with our lawyers to make sure that it is lined up for that.

Ms. Helena Jaczek: Then, as you were describing, looking beyond at other provincial jurisdictions in terms

of not just this incident but perhaps more oversight over pharmaceutical procedures in general—you mentioned, I think, when you were here last, that British Columbia has more oversight in terms of what the college does?

Mr. Marshall Moleschi: Sure. In Ontario, hospitals are specifically exempted, whereas, in six or seven of the other provinces, the colleges look after both the community pharmacy and the hospital pharmacy. They have oversight in both those areas and have developed standards.

British Columbia is one area. A consultant is coming from British Columbia with their knowledge to be able to do this. This person is also a past director of pharmacy and actually a director of pharmacy for a whole region, so he's got a significant amount of experience. We will value that experience to be able to do that.

Also, what we're talking about is one step, and there are other steps that are taking place. There are steps that are happening with Health Canada, for example. I've probably been on the phone almost daily with Health Canada, with key people, to be able to do that.

We've had one teleconference where all the registrars right across Canada had been on with key people with Health Canada to help understand what the grey area was—what isn't looked after—so that we can focus on those areas. On the 15th of May, we're actually hosting all the registrars coming together face to face and spending time with Health Canada to be able to look at that.

We will put our systems in place, and they will look after pharmacies, and then these new entities that, over the evolution of time, have sprung up—we need to be able to look at them. But there's also a role for Health Canada, especially to do with their establishment licences and those things, and we will work together to make sure that there isn't a grey area going forward.

That's going to take a little bit of time, and it will take coordination, but there is an effort to do that right across Canada.

Ms. Helena Jaczek: Just to clarify: When you say you don't have oversight over hospital pharmacies—obviously, the pharmacists employed by hospitals must be accredited by the College of Pharmacists, correct?

Mr. Marshall Moleschi: We accredit pharmacies that are community pharmacies, that fill prescriptions on a retail basis.

Ms. Helena Jaczek: Right.

Mr. Marshall Moleschi: The pharmacists are registrants of ours, whether they're in community or hospital practice.

Ms. Helena Jaczek: Right.

Mr. Marshall Moleschi: And the pharmacy technicians are registrants of ours. It's just that we don't yet, at this point in time, have the ability to go into a hospital and look at their processes like we can on a community pharmacy site.

We can look at misconduct of an individual who was a registrant of ours, to see—well, there are several things we can look at. Their entry to standard to practise: We

look at them when they enter into the practice. They need to demonstrate to us on a periodic basis that they've maintained their competency—

Ms. Helena Jaczek: Through continuing education, or how?

Mr. Marshall Moleschi: It's continuing education, and we have a process that's a little more sophisticated than just continuing education. There's a testing process and a sampling process. Hospital pharmacists fall into that category as well, so we have the ability to do that.

If there's any alleged misconduct by a registrant—whether they're a pharmacist or a technician—in any part of their practice, we would have the ability to go and investigate that.

What we don't have the ability, as the college, is to look at the processes that a hospital would have. That's what British Columbia and six other provinces have. They can go in, do an inspection of a hospital pharmacy, and see if their processes meet today's current standards. Do they have the policies and procedures there to be able to ensure, if something goes wrong, that things are notified? Do they meet standard 797? Do they have other standards that meet the Canadian Society of Hospital Pharmacists' best-practice standards as well? Those are the types of things that a college would do if we had authority on that side.

We'll use some of those things to be able to look at these premises. There's a lot of parallel between those hospital inspections and the drug preparation premises. The drug preparation premises just aren't doing it patient-specific, but a lot of their processes will be the same, and we'll look at those opportunities to be able to do that.

Ms. Helena Jaczek: Explain to me how you inspect a community pharmacy. Do you go in a surprise visit? Do you watch them compound a medication? Do you look at records?

I'm coming partly from a physician background where, obviously, the College of Physicians and Surgeons can come in and take your patient records and make sure everything is documented correctly. I'm also thinking of my public health inspectors, who literally watch how the chicken is cooked start to finish and measure temperatures and do testing along the way. Can you detail what exactly happens during a community pharmacy inspection?

Mr. Marshall Moleschi: Yes, I could. Before opening, there's an inspection that takes place to make sure that everything is there and they have everything lined up to do that. That's a scheduled type of inspection. Those sorts of things, before a community pharmacy opens, they need to go through that process. There's hundreds that open every year, so there's lots of those that take place.

Shortly afterwards, we'll be there to watch the operation and, yes, we do look at the patient interaction. We look at the records that they've kept. There's a checklist that they go through, and that checklist is a checklist to guide them through a process, but they're also trained to

be able to look at if there are any issues around safety, sterility and those sorts of things.

We look to see if they're dealing with any speciality types of areas well. If there's methadone, we spend particular due diligence to make sure that those processes are in place to make sure they have narcotic reconciliation that takes place on a regular basis. We look at the interaction. Now that pharmacists are making decisions about refills of prescriptions and those sorts of things, we'll look at those processes and the documentation around those processes. If they're doing compounding, we'll see to what standards they're doing it and whether it's sterile compounding versus regular non-sterile compounding, where you put in ingredients to get the creams and the ointments and those sorts of things. We'll look at the types of expiry, those sorts of things that they have in process.

Those are looked at, and then recommendations could come out of that if there were those sorts of things needed.

Ms. Helena Jaczek: Well, it sounds very thorough. In a pharmacy—a community, retail pharmacy—how often is a solution made of a drug to a certain concentration in a batch that can then be withdrawn for an individual patient? Does that happen at all? Or is it always sort of patient-specific, a specific dose compounded?

Mr. Marshall Moleschi: Our standards would be that it would be patient-specific, so that is the way things would be prepared: patient-specific. That's how we would determine whether it was a pharmacy versus manufacturing process. We've used tools like—I think it's POL-0051—the federal government's compounding versus manufacturing standard to judge that. It lists criteria for that: Was it in a patient relationship? Was it patient-specific? Those sorts of things.

But I will tell you that sometimes there are grey areas, and there are times when it would be very safe and effective to anticipate that there is going to be a group of patients that come that day. It would be very, very confined, but it could be done for a certain day, to be able to prepare a preparation because you're in that business, and you know you're going to have that many patients coming in. I think if you're a physician and you're familiar with the allergy testing type of stuff, sometimes physicians will prepare it for a group of patients that are coming in that day because that's the way it's going to work.

That is the exception, and we do try to allow for those sorts of exceptions. We'll look to see to make sure there are policies and procedures in place to handle those. I won't say that there's never an exception to that, but it has to be either specific to that patient or the real exception would be specific to a small group of patients.

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Ms. Helena Jaczek: You mentioned about the communication with other jurisdictions—Health Canada and so on. Would you say there's a move to have some uniformity as it relates to this compounding grey area across the province?

Mr. Marshall Moleschi: There's absolutely a move for uniformity. There's absolute concern that there may be an area that we didn't realize was out there; that our health care system has evolved and maybe our practices, as colleges, need to make sure that we reflect that new evolution. Certainly, there's a concern and a huge desire. I was able to call this meeting next week on very short notice. As a matter of fact, the agenda hasn't even all been prepared, but there is a desire right across Canada to be able to make sure that this area—it's called a grey area, that we didn't realize was there—be addressed. So, yes, there is a desire to be able to do that. I sense that with my peers in colleges right across Canada and also with Health Canada and provincial governments as well.

Ms. Helena Jaczek: Your inspector that went out—I think it was in January of this year—was, I guess, very aware. Again, that was good that it was noticed that there were these two facilities—Marchese Health Care, the pharmacy, and Marchese Hospital Solutions adjacent. There was an inquiry made, I guess, of the manager of the accredited pharmacy that Marchese Hospital Solutions was operating under the Public Hospitals Act, she said. How would your inspector have interpreted that? What did that mean?

Mr. Marshall Moleschi: So, the inspector would be aware of 0051, which talks about compounding versus manufacturing and that compounding is done in hospital-specific—I'm sorry; the compounding is done patient-specific. On the hospital side of things, if it was done in bulk, it would fall under manufacturing. She was aware enough, even though she's a community pharmacy inspector—because we don't look after the people trained for the hospital side. We will train people and we do do these new areas. She was aware that there was some activity that didn't seem consistent with that pharmacy. That was the response, so she has recorded the response that she got from the staff. The response that she got from the pharmacy staff was that it was done under the hospital act. I don't think there's follow-up as to how that pertained at that time.

Ms. Helena Jaczek: I see. Would you have any insight as to what that might have meant or what Marchese Hospital Solutions thought it meant?

Mr. Marshall Moleschi: I wouldn't have any insight. There were further questions that that inspector did. What they said is that because they relayed to her, that inspector, that they are pursuing an established licence under Health Canada, the pharmacy should let them know of the progress of Marchese Hospital Solutions under their interaction with Health Canada.

Ms. Helena Jaczek: Did your inspector make a note of what was going on on the Hospital Solutions side, like which drugs were being compounded, was it concentration-specific or patient-specific? I know she really didn't have jurisdiction, but did that come up?

Mr. Marshall Moleschi: I only can read from her report. From her report, she just saw some activity and some paperwork that didn't seem consistent with the pharmacy activities that seem to be associated with

another type of activity. So, that inspector did not go into—

Ms. Helena Jaczek: Which was not patient-specific?

Mr. Marshall Moleschi: It was not patient-specific, and asked the questions and came up with the responses that we've recorded. That person did not go into the Hospital Solutions side of the building, which was separated by doors and rooms before you got over to that area, I later found out.

Ms. Helena Jaczek: Thank you. We'll save whatever time we have left.

The Chair (Mr. Ernie Hardeman): You have one minute left. With that, Mr. Yurek?

Mr. Jeff Yurek: Thank you, Chair. How are you?

Mr. Marshall Moleschi: Fine.

Mr. Jeff Yurek: Good to see you. Just a few questions: When you talk about what was mentioned about the batching in the pharmacy if you knew all your patients were coming the one day, I've always known that the underlying principle from the college is to put the public protection ahead of anything else. As long as you've got that as a guidance, you should be fine. Is that pretty accurate?

Mr. Marshall Moleschi: That's an underlying principle of all the things that we're doing. When we develop rules and regulations, they should all support that underlying principle, as we're doing that in the patient's best interest for the best patient outcome. That's part of what I'm emphasizing when I go around talking to groups. There are rules and regulations and there are bylaws that we have, but to have that public protection is ultimate.

Mr. Jeff Yurek: Are all hospital pharmacists registered with the college now?

Mr. Marshall Moleschi: All hospital pharmacists are registrants with the college, yes. That's changed, and I don't know the year that that changed, but it changed maybe 10 or 15 years ago. There was a time in Ontario's past where they weren't registered with the college; the college just looked after community pharmacy. But the world has evolved.

When I graduated, probably 5% of all pharmacists were on the hospital side. Now, a full 20% of pharmacists that are registered with us are on the hospital—only 60% are on the community side and then there are pharmacists who are like me, or some consultants or maybe other people—and I'm not sure where you are, Jeff—

Mr. Jeff Yurek: I'm not there yet.

Mr. Marshall Moleschi: You're not there yet. They are not working in a community pharmacy or a hospital pharmacy, but they have a consulting business or they're on family health teams or areas like that.

Mr. Jeff Yurek: Speaking of the evolution of, I guess, pharmacy: Would the college be willing to take over regulation of hospital pharmacies?

Mr. Marshall Moleschi: If we were asked, we would be willing. We think that that's an important area for oversight. There's a need to have oversight over that area as well, and I think the hospitals would like that too. Even though accreditation of the entire hospital is a vol-

untary process, you see hospitals wanting to go through that process. I would say that they want to go through our process where their labs or pharmacies and those different types of areas would also have oversight. That's specific to that profession, and I think that's really important.

I can't speak for council because it hasn't been put to council, but as the registrar I would put that forward to council.

Mr. Jeff Yurek: Just to the grey area, you said there was that area that Marchese fell into; that there's really no oversight. Has the Ministry of Health ever contacted the College of Pharmacists and said, "Hey, we've got this problem here. Can you help us solve it? There's a bunch of unregulated activity going on out there"?

Mr. Marshall Moleschi: Not prior to this. I think we both realized it at about the same time. It was the same day, and I forget the day that—it was the 3rd or 2nd, I think, when I got back from vacation, and I made calls to the ministry. I made calls to Health Canada when I saw the reports that were out there. We then got together with Health Canada to do a joint visit to the accredited pharmacy and asked permission to go into Marchese Hospital Solutions. So, at that time, they realized it, but I think it was at the same time as I realized it.

Mr. Jeff Yurek: With regard to pharmacy registered technicians, can you explain to the committee how technicians have evolved over the last four or five years and why in a hospital some would be registered with the OCP and others wouldn't?

Mr. Marshall Moleschi: Sure. Pharmacy practice has evolved, and the profession has evolved, over the years. When I graduated, there weren't pharmacy assistants or pharmacy techs. Very few pharmacists were filling the prescriptions and giving advice about their medications. But with time, there was a need for pharmacists to focus more on the clinical aspects of things and some of the distribution things. We called them technicians at the very beginning, but they're really assistants. They were non-regulated people who came in—pharmacists could delegate a task to them, but they couldn't delegate any responsibility. There was a whole variety of training. There wasn't a standardized training for people who were in that assistant role.

About 10 or 15 years ago—and Ontario was a lead—Ontario identified that there was a need for a standardization for the education of these people and a need to have a scope of practice, that there be a fence around the types of things that they could do; so, identify what that could be.

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Then in 2005-06 British Columbia, Ontario and Alberta moved together toward developing a health care professional that was called a regulated pharmacy technician; now it's just a pharmacy technician because it's a reserved title. That person would be registered with the college. They would have attained a certain level of education and demonstrated a certain level of skills, knowledge and ability to practise to that level, and a

commitment to ongoing learning, so they've become a health care professional.

There is a very defined scope that they can do, and it's to do with the distribution side. It has nothing to do with the clinical side. But that could free up the pharmacist to spend more time on the clinical side to do that.

At the same time that this has developed, there are people who have been assistants; they're not regulated. We have a pharmacist who's regulated, and now we have a pharmacy technician who's regulated. But there are people working in pharmacies who are not regulated, and they can be assigned certain tasks, and it's appropriate that they do that. But no one can delegate away the authority and the responsibility; it would still be the pharmacist's responsibility and authority. They could do some less technical tasks, and that takes place.

There's an evolution now to bridge from unregulated to regulated. Not only can you go through a two-year program to go through that, but people who have not been regulated and didn't go through the two-year program, if they've got experience, can actually bridge that by taking about a year and a half worth of courses to do that. That's in place in Ontario, British Columbia and Alberta, but it's something that's moving right across Canada. In the last few weeks, there were some meetings at the national level to standardize that and bring it under one umbrella that's national, so each one of the provinces has the same model.

Mr. Jeff Yurek: Just before I hand it off, do you guys have questions?

You've noted here that there are 3,567 community pharmacies. Over the past few years has that number stayed the same, increased or decreased?

Mr. Marshall Moleschi: The number has actually increased over the last years. Now, realize that there are pharmacies that close and pharmacies that open. There are hundreds that open and close. But on a net basis, every year—I think over the last five years—there's been a 100% to 150% net increase in the number of pharmacies.

Last year was a year where a major chain actually closed down, and there still was a net increase. The major chain was Zellers, but there still was a net increase in the number of pharmacies that were there. There's a large opening of a chain this year too, so it has been increasing.

Mr. Jeff Yurek: With the increase in pharmacies and now this regulation adding more for your college to do, will the college be able to handle all of its tasks?

Mr. Marshall Moleschi: We will do our best to fulfill our mandate to protect the public.

Mrs. Jane McKenna: I just have one question for you. Thank you so much for coming here today. We've had a handful of people who have come into this committee who have all sat down to acknowledge that there's a grey area. We had Ms. Zaffiro, who came in to say that when she found out she was getting the RFP, she phoned Health Canada and phoned you people as well to see if she needed to get regulated because it was a grey area.

I guess my question is, if all of these people seem to be talking about the same thing, how come both of you—

Health Canada and yourselves—didn't get this from anybody else?

Mr. Marshall Moleschi: It's the question that we're asking ourselves as well. We did receive an inquiry, and it was over a year ago, from that group, and I've got records of it. We've done a fairly comprehensive review, and we came up to say, "This is not patient-specific by 0051; it looks like it's manufacturing. You need to talk to Health Canada."

My understanding was that there were ongoing discussions with that, and we actually had not heard back from them since then, other than this one encounter when I went through the records. Looking back, this one inspector did find a reference to Marchese Hospital Solutions in the January 2013 inspection, and we asked more questions about that. Should we have been on it more quickly? I would have liked to have been on it more quickly. We are on it now.

Mrs. Jane McKenna: Yes, that's wonderful. I guess the bottom line, I think, is that when people are in the system, and they're trying to answer the questions that they figure they should be being asked themselves, it will be an unbelievable opportunity to see the overlap and the gaps that were there, because clearly there were red flags along the way numerous times, and somehow that gap was just missed.

Thank you for your answer for that.

Mr. Marshall Moleschi: Our meetings with Health Canada are to make sure that that's looked after. I think it has been mentioned earlier today that Baxter is also—their process needs oversight as well. But a while ago, I went to Health Canada's website and I looked up Baxter, and they had three establishment licences. I assumed, and I assumed incorrectly, that this type of activity was covered under those establishment licences. What we're learning in this next little while, why it's so important that we get together, is that we need to understand Health Canada's processes a little more clearly than just the 0051 that we're taking as the rules that would divide between compounding and manufacturing; that it is more complicated than that. That's why we're doing these face-to-face meetings right now: to make sure that those gaps are identified.

I guess the assurance that I'd like to give to you, as overseers of all systems, is that it's important not only to identify that but we have processes in place so that we continually look at any gaps that may—because the world's going to evolve with time as well.

Mrs. Jane McKenna: Thank you.

The Chair (Mr. Ernie Hardeman): Ms. Elliott.

Mrs. Christine Elliott: Thank you, Mr. Moleschi, for coming back before the committee. I just have two quick questions. One relates to the initial contact by Marchese with the college in late 2011/early 2012, where they were providing you with a detailed description of the work that they were proposing to do. I'm assuming that was in writing and there was a back-and-forth between them and the college.

Mr. Marshall Moleschi: Yes, there is a back-and-forth.

Mrs. Christine Elliott: Would you undertake to provide us with copies of that correspondence?

Mr. Marshall Moleschi: I will.

Mrs. Christine Elliott: That's great. Thank you.

Secondly, with respect to the routine inspection earlier this year, comments were made that there was some overlap between Marchese Hospital Solutions and Marchese Health Care. Would you be able to provide us with a copy of the report, if any, that was provided?

Mr. Marshall Moleschi: I will provide you with that interchange, yes. I will.

Mrs. Christine Elliott: All right. Thank you very much.

The Chair (Mr. Ernie Hardeman): Okay. We'll go on to the third party. Ms. Gélinas.

M^{me} France Gélinas: Thank you. While we are asking for documents—this is more for the Clerk so that I don't forget. Medbuy did not submit the two proposals that came from Baxter and from Gentès and Bolduc; they only gave us the one from Marchese. If you could do a follow-up on that.

Sorry; that had nothing to do with you.

Mr. Marshall Moleschi: No, that's fine.

M^{me} France Gélinas: It's nice to see you again. I listened to some of the answers you've given. Some of my questions will repeat a bit, but it's for clarification. The first one, just keeping on the track where my colleague was going: On page 3, you talk about, "On April 4, the college, with Health Canada, reviewed the respective memos of the joint visit to the premises from the day before and developed next steps which included the development of specific questions for the identified members." If you could please table those questions with the Clerk as well as the answers that you got, once you asked those questions.

Then you go on to say, "having confirmed the distinction between Marchese Health Care pharmacy ... and Marchese Hospital Solutions (the federal corporation contracted to produce the medications ...), the college publicly acknowledged that Marchese Hospital Solutions was not an accredited pharmacy."

You are the only one that can accredit a pharmacy. Health Canada can't do that.

Mr. Marshall Moleschi: No, we wouldn't be able to accredit the pharmacy; it would have to get an establishment licence from Health Canada.

To be clear, the activities that Marchese Hospital Solutions was doing were not activities of a pharmacy. One of the things we had to do in that time was to find out not only what it was that they were doing, but also to go through records to see if there's anything that was patient-specific, which would have put them as an unaccredited pharmacy doing a pharmacy type of work, and we wanted to make sure that that wasn't taking place. In that investigation, we did not find anything that was patient-specific that Marchese Hospital Solutions was doing.

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M^{me} France Gélinas: Okay. Did you find anything that was outside of what they had told you they were

going to do? Remember the letter that my colleague asked for in late 2011/early 2012? They asked the college for clarification on the regulation requirements for a start-up business providing non-traditional pharmacy services. Were they doing exactly what they had said they would do?

Mr. Marshall Moleschi: To my best recollection, it was what they said they were going to do.

M^{me} France Gélinas: Okay. And you will share the—

Mr. Marshall Moleschi: What they had proposed that they were going to do, I'll share that with you.

M^{me} France Gélinas: Okay. You also, just before this, you said, "During that session, the college shared with Dr. Thiessen a full chronology, which we had already shared with the ministry, of all correspondence between the college and Marchese Hospital Solutions and Marchese Health Care pharmacy." If you could please table those with the Clerk as well, that would be—

Mr. Marshall Moleschi: Those would be one and the same as to what this is, as well as my opening remarks with the chronology. So, I will, but I wouldn't expect a whole lot different than what you just asked for.

M^{me} France Gélinas: Okay. I just wanted to make it clear.

The next one is on page 5 of your opening statement, where you're talking about a routine inspection that was done in January 2013 of the health care side, Marchese Health Care. Then you said: "Notes reflect that the designated manager of the accredited pharmacy indicated that Marchese Hospital Solutions was not regulated or inspected by Health Canada at this time, but was operating under the Public Hospitals Act."

Mr. Marshall Moleschi: She wrote that down to reflect what she was told by the pharmacist.

M^{me} France Gélinas: Okay. Do you know this to be true?

Mr. Marshall Moleschi: I do not. That's a reflection of what she was told. She then said, "Report back to us on your discussions with Health Canada on getting an establishment licence."

M^{me} France Gélinas: Okay. You call it, in your report, the "designated manager." If you could share the name of the designated manager with the Clerk, that would be helpful also. I take it that it's a designated manager at Marchese Hospital Solutions who said that.

Mr. Marshall Moleschi: No, it would be the designated manager in the pharmacy that—

M^{me} France Gélinas: The pharmacy side. It gets complicated quickly, doesn't it?

Mr. Marshall Moleschi: It does get complicated. There isn't a designated manager on Hospital Solutions in our regulations because that wasn't something we regulated. Until it has gone through all the posting, we won't, until that time.

M^{me} France Gélinas: All right. So the ministry has now put a draft regulation, and you're going through the process of having them basically becoming regulations for your college to follow. I was quite surprised when you mentioned that you are inviting voluntary identifica-

tion and, potentially, inspection prior to authority being received. Can you tell me more about that?

Mr. Marshall Moleschi: That's what I will be proposing to our council in the Friday meeting.

There are timelines that go out a long way, and I sensed an urgency to be able to act as quickly as we could, so we're putting as much in place ahead of the regulations. The regulations will have to have the time that's laid out in law, and that's 90 days, but I do anticipate that we should be able to get timelines—that we could ask people to voluntarily identify themselves before the regulations go into effect. That would give us a head start in doing this in a timely way so that when the regulations come into force—probably in September—we'll have already looked at some. I can't force them into that, but I could ask people to do it voluntarily, and I think a significant number of individuals who are pharmacists or pharmacy technicians would be able to do that.

We're also looking at putting our processes in place with our standards in place that we could also look at some facilities before the September deadline—maybe in August—to be able to get a head start on some of this, so that when it goes into place we would have a head start on a lot of this.

We're putting a lot of things in place now. While I can't force people to go through our process till the regulations are in place, I could ask them if they would participate. That's the idea behind those sentences.

M^{me} France Gélinas: So you feel that your college has the competence to do that oversight?

Mr. Marshall Moleschi: My college will contract with others to be able to make sure that we have that and build on the experience of others. I have a consultant who's coming on a plane tonight to spend tomorrow and the next few days, and I've got a commitment from the registrar from another province to share his expertise to be able to help us with that.

Will it be the answer, a panacea to everything? No, but it will give us a head start, and that's what I'm looking for right now.

M^{me} France Gélinas: So acquiring those competences is something that you're working on and that you feel you can acquire?

Mr. Marshall Moleschi: Absolutely, and we need training. We, up until now, had been focused on the community side, and I think we do a good job of that, but there is a different degree of competence and a different competency set that we need to be able to do this sort of facility on the hospital side, which are more alike than it is on the community side.

M^{me} France Gélinas: You say that you feel a certain amount of urgency to move on with this, which is why you're having voluntary identification—inviting people for that. Could you describe this? What kind of urgency?

Mr. Marshall Moleschi: I think the people of Ontario—and our society in general, right across Canada—deserve to have confidence in their health systems. If we're a part of that health care system, we as a college

have a role to assure them that there are things in place so—it's not that nothing can go wrong, because things do go wrong in the health care system, but that there is oversight, that they can learn from those things that do go wrong and that we have a way of continuously improving our systems.

It's not just that we get a solution for today, because the world will evolve with time. We need to find a way to continuously look at the way things are evolving and evolve our systems to be able to do that. That's our commitment. Our commitment is to restore public confidence in the system. Pharmacy and pharmacists are a very respected profession, and that's important to the profession.

We are the organization that assures the public that they do meet that standard, and that's what we're trying to do by oversight of this alleged gap or this grey area: to be able to put in a system so that we can assure the public that there will be a system to deal with this.

M^{me} France Gélinas: I agree; oversight brings reassurance.

Mr. Marshall Moleschi: Yes.

M^{me} France Gélinas: You explained to my colleague that you were under the impression that Marchese came to you—came to the college. The college checked—they were not a pharmacy—and therefore could not do accreditation for them. You sent them to Health Canada and were under the impression that there was no grey zone, that Health Canada would do their job. I guess that explains why that urgency did not come before.

Mr. Marshall Moleschi: We gave them an alternative, to be able to look at their business model, and I guess the assumption that we made is that they wouldn't go forward with the business model until they were regulated by one of the two.

M^{me} France Gélinas: Okay; but they did. The Ministry of Health, though, knew that there was that grey zone, and they've known this for quite some years. Have they ever gone to the college to have a discussion about the grey zone?

Mr. Marshall Moleschi: I don't know if the government knew or did not know. They had not come to me with that discussion before this had taken place. The discussions that have taken place have been with Health Canada. It wasn't particularly around this, but other areas in the interpretation of 0051, where we saw some issues with putting those things into—operations, I guess.

M^{me} France Gélinas: You're looking to the wrong person if you want help pronouncing a word here.

Mr. Marshall Moleschi: I'm sorry.

I think that's the right thing to do: have regular meetings to be able to see if there's a disconnect—whether we need to refine the way we're interpreting it.

Meetings did take place last spring around 0051, and there was a meeting in June that I didn't participate in, where it was on the agenda. But, certainly now it's the subject of whole meetings, not just one agenda item.

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M^{me} France Gélinas: Okay. So the subject had been discussed before, as one of many, on at least two occa-

sions that you know of. But now, not only will we talk about it; action will follow.

Mr. Marshall Moleschi: Yes, and it wasn't in this context. It was to do with how we both could work with 0051, the difference between manufacturing and compounding, and different issues.

M^{me} France Gélinas: If we look specifically at the level of risk every time there is a hand-off—it used to be that the hospital prepared those chemo drugs patient-specific. They put it together; it was going to a patient. People knew exactly how the drugs were going to be used. They were part of a team. We now have four levels of hand-off: the hospital to Medbuy, Medbuy to Marchese, Marchese back to the hospital and then the hospital pharmacy to the actual patients.

When we look at some of the detailed policy that your college has done to ensure that safety and quality can be maintained in various settings, I'm kind of surprised that we didn't see any detailed policy as to: How should pharmacists handle that level of risk by those many, many hand-offs that a subcontracting-out of pharmacy work would bring?

Mr. Marshall Moleschi: The question is, because it is a several-step process, why weren't we involved in—the simple answer is that we have been focused, based on our acts and our regulation, on the community side. We weren't involved in the drug distribution side on the hospital side. That, in Ontario, has been part of the process. So it is there.

My experience in British Columbia—because I was a hospital pharmacist and a director of pharmacy in my past, as well as a hospital administrator. In almost all my career, which goes more than 30 years, there have been some products that have been prepared by Baxter or Abbott at one time. So that does go back a long time. Buying some things in mini-bags—cefazolin—was not unusual in British Columbia.

M^{me} France Gélinas: Or in Ontario. So because it had been done for a long time, nobody is blinking an eye?

Mr. Marshall Moleschi: I don't know.

M^{me} France Gélinas: As a pharmacist, could you ever see a clinical use for four grams of cyclophosphamide to a single client?

Mr. Marshall Moleschi: I'm not up to date on my clinical side of things, so it would be hard for me to answer that. I would look it up in a book if I was asked that question.

M^{me} France Gélinas: And quickly—I can give you my Google and you would quickly find out that it is not all right.

I'll let it go around once. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Jaczek?

Ms. Helena Jaczek: Thank you. Your involvement with Dr. Thiessen's report is considerable, I assume?

Mr. Marshall Moleschi: My involvement is to provide information. "Considerable" was one afternoon, but there are daily conference calls that go on, and I'm on those calls.

Ms. Helena Jaczek: And with the working group with the ministry?

Mr. Marshall Moleschi: That's the daily—

Ms. Helena Jaczek: That's the daily.

Mr. Marshall Moleschi: Yes.

Ms. Helena Jaczek: Yes. Actually, I just have one little question.

The Chair (Mr. Ernie Hardeman): And you only have time for one little question.

Ms. Helena Jaczek: Good. We have heard from Peterborough that a pharmacy assistant detected the error. Who is a pharmacy assistant? You've referenced pharmacists and pharmacy technicians.

Mr. Marshall Moleschi: Pharmacy assistants are people who are not regulated by the college. They have a job description where they do tasks in a pharmacy, but they have to be checked by someone who's regulated. That person would have had a certain amount of training, but they hadn't gone through the process to become a regulated pharmacy technician, which is graduating from either an accredited program or going through, for a temporary period of time, a bridging program. It's essentially going through an accredited program, writing national exams for a regulated technician, and then being accepted by us as a registrant or a health care professional in good standing. That person likely just hasn't gone through that process at this time. It doesn't mean that their work is less valuable; they would just have certain work to do, and it would be involved in preparation. That person seemed to be on the ball.

Ms. Helena Jaczek: Very much so.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time for the government side. The official opposition: Mr. Yurek.

Mr. Jeff Yurek: Do I have time for one—

The Chair (Mr. Ernie Hardeman): You have all kinds of time—you have seven minutes left.

Mr. Jeff Yurek: With regard to the college investigation into Marchese now: It's purely just pharmacist-specific because that's really all that you have jurisdiction over?

Mr. Marshall Moleschi: Yes. Our investigation is into members, so they're people, they're pharmacists. Two people are on that investigation. It will be to determine whether there's any professional misconduct that has taken place as they've exercised their scope of practice.

Mr. Jeff Yurek: So any member outside of a typical defined pharmacy working out in the community—you would be able to investigate their professional performance?

Mr. Marshall Moleschi: We could investigate any registrant of ours, which would be a pharmacist or pharmacy technician, to do with professional misconduct.

Mr. Jeff Yurek: That would most probably just be complaint-driven if they're not a typical pharmacist?

Mr. Marshall Moleschi: Yes, that would be very typical. It would be unusual to do what I did: initiate a registrar's investigation. Based on the seriousness of the

issue, we wanted to discover as much as we could as quickly as we could, and that's why I initiated a registrar's investigation.

Mr. Jeff Yurek: You said you'd feel fine with overseeing hospital pharmacies. I'm throwing this out there for the committee. Would it be fine if you oversaw third party outsourcing, like Medbuy and such, and give them a little oversight?

Mr. Marshall Moleschi: I don't know.

Mr. Jeff Yurek: That's it, Chair. Thanks.

The Chair (Mr. Ernie Hardeman): Any more? If not, we'll go to the third party. Ms. Gélinas?

M^{me} France Gélinas: Okay; thank you. I want to come back to—have you seen the label that Marchese had on the—I'll take the cyclophosphamide. Have you seen the label that they had put out?

Mr. Marshall Moleschi: I have not seen the label. Perhaps staff may have, but that investigation is separate from—because I'm involved in the Thiessen, we've tried to keep those roles very separate.

M^{me} France Gélinas: Okay. In your 30 years of working as a pharmacist, would you say that it is part of your job as a pharmacist to check if an IV drug is to be prepared as concentration-specific or not?

Mr. Marshall Moleschi: I think it's part of the pharmacist's job to know how that drug—whichever way you prepare it—is going to be used, and make sure that you're contributing to the best health outcomes of the patient. A pharmacist should know how that's going to be used down the road.

M^{me} France Gélinas: When Marchese came to committee and told us that they assume that the drug was going to be used for a single patient, there is an easy way to check that, is there not?

Mr. Marshall Moleschi: They had a business model, and there's a third party involved, like Medbuy. I don't know any of the diligence that was done during that time.

M^{me} France Gélinas: Who do you figure—I know that he just asked a question and you were noncommittal, but as we are seeing more and more—I now have a book full of those medications that are being subcontracted out. Lots of them are IV drugs; in that particular section here, they're all IV. All come with the same labelling where you have no idea if the overfill has been accounted for or not. The pharmacist's judgment will tell you that sometimes it matters and sometimes it doesn't, because you know how the drug is to be used for the benefit of the client.

Given that there is no oversight of that four-times-hands-off process—and you spoke so eloquently of what oversight does to our health care system. It brings reassurance—it doesn't catch it all—but it brings reassurance; it brings best practices; it brings value. Who should oversee?

Mr. Marshall Moleschi: We're going to do our best to oversee where we have responsibility as laid out in regulations and bylaws. We will work with others to help assure the whole system that everyone is working together, and we'll do our best to be able to do that. We

will be even more diligent going forward in the future that if we see any areas that need to be addressed—it will be an education process even for our staff, but if anything raises a flag, that we have a process to be able to bring that to an area where we can identify and take action amongst a group of different organizations, federally or provincially.

You see police forces working at different levels—local police and national police—on different issues. Perhaps—and I'm not going to say that we're police, because we're not. We're actually in a profession and doing that. But we could learn from that as well, to look

at ways we can coordinate some of our activities, as society evolves and the health care system evolves—that we can be best positioned to reassure the public that their system is safe and effective.

The Chair (Mr. Ernie Hardeman): Thank you very much. That does conclude the time. We thank you very much for being with us again today to enlighten us even further about the pharmacists involved in the situation. Thank you again for coming.

There being no further business, and we have no further delegations today, we stand adjourned.

The committee adjourned at 1632.

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Standing Committee on Social Policy

Oversight of pharmaceutical
companies

Comité permanent de la politique sociale

La surveillance, le contrôle et la
réglementation des entreprises
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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Tuesday 7 May 2013

Mardi 7 mai 2013

*The committee met at 1601 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIES

The Chair (Mr. Ernie Hardeman): I'll call the meeting of the social policy committee to order this afternoon. We are here on the study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

We have two delegations this afternoon. Just before we start the delegations, I just wanted to clarify—and this is for the media that is with us today—that we've had some concern in the last number of days about the media and the cameras interfering with the members along the committee table. You're quite welcome, and we're happy to have you here, but we would hope that you would stay either behind the Chair or behind the presenters but not along the two sides in the committee room. Okay?

With that, we thank you very much for being here. In order to start the hearing, we do ask that the witnesses be sworn in or affirmed, and we'll turn it over to the Clerk to get that done.

The Clerk of the Committee (Mr. William Short): I'll start with the first witness. It's Craig Woudsma?

Mr. Craig Woudsma: Yes.

The Clerk of the Committee (Mr. William Short): You wanted to be affirmed?

Mr. Craig Woudsma: Yes, please.

The Clerk of the Committee (Mr. William Short): Mr. Woudsma, if you could just raise your right hand, please. Mr. Woudsma, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Craig Woudsma: I do.

The Clerk of the Committee (Mr. William Short): Okay. Ms. Turner, you had asked to swear an oath?

Ms. Judy Turner: Yes.

The Clerk of the Committee (Mr. William Short): Thank you. Ms. Turner, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Judy Turner: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Mr. McLaughlin was already been sworn in.

The Chair (Mr. Ernie Hardeman): Mr. McLaughlin has been sworn in. We welcome you all here.

MR. CRAIG WOUDSMA

The Chair (Mr. Ernie Hardeman): We'll start the day with Mr. Woudsma. You will have 10 minutes to make a presentation, and you can use all or any part of that. When your presentation is finished, we will have 10 minutes from each party to ask any questions of your presentation. That circulation will start with the official opposition this time around. With that, the floor is yours to make your presentation.

Mr. Craig Woudsma: Okay. Thank you very much, Mr. Chair and ladies and gentlemen of the committee. I would like to begin my remarks by thanking the committee for supporting our request to limit today's statements to myself and my colleague Judy. Our pharmacy, which is assigned to the cancer clinic, has a normal complement of four assistants and one senior assistant, for a total of five.

With one of our colleagues on medical leave and the quality assurance processes requiring at least two assistants—

The Chair (Mr. Ernie Hardeman): Excuse, me. Could you speak into the microphone?

Mr. Craig Woudsma: I'm sorry. Is that better?

The Chair (Mr. Ernie Hardeman): That's much better.

Mr. Craig Woudsma: Do you want me to start over?

The Chair (Mr. Ernie Hardeman): No, that's fine. Carry on.

Mr. Craig Woudsma: Requiring the attendance of three of us would have resulted in the clinic's closure for one day and the cancellation of up to 45 patients. Judy and I sincerely appreciate your flexibility and understanding, and I am pleased to say that the full schedule of patients will continue to be treated today.

My name is Craig Woudsma, and beside me is Dr. Peter McLaughlin, who I am certain you will remember from his attendance before this committee on April 30.

I began my interest in pharmacy as a co-op student in high school during a placement in a retail pharmacy in Cobourg, Ontario. Following this experience, I began my studies in health sciences for one year at the University of Toronto and then subsequently transferred to Trent University in Peterborough to study English and history.

Throughout my studies, I continued to work in a retail pharmacy setting for a total of 10 years.

In 2007 I was certified through the Ontario College of Pharmacists and began to work at the Peterborough Regional Health Centre in the fall of 2009. After two years at PRHC, I received in-house certification to work in oncology in 2011.

I am pleased to report that I wrote my board examinations on March 20 of this year, three days after the incident, and I am in the final stages of registration as a pharmacy technician. My jurisprudence examination is scheduled for May 23. I am a member of the code brown hazardous materials spills and the code white violent individual teams, a union steward and a two-term co-chair of PRHC's occupational health and safety committee.

I realize that you've heard a detailed account from Laura Freeman during her testimony on April 30. Laura's report to you was quite in-depth so I will attempt to avoid duplication.

On the morning of March 20, 2013, the supply of gemcitabine from Baxter, the previous supplier, had been depleted. As part of the prescribed treatment regime, a patient scheduled for the afternoon was to receive gemcitabine. The new supply of gemcitabine was from the new supplier, Marchese, and was used for the first time that afternoon.

The new supply of Marchese gemcitabine stock was located in our pharmacy's refrigerator. My fellow pharmacy assistant noted at that time that, unlike the new Marchese bag, the previous Baxter supply did not require refrigeration.

As is our normal quality assurance process, I reviewed the label on the Marchese product. Unlike the bag of the predecessor supplier, neither the total volume nor the final concentration were included on the Marchese bag.

As the Baxter bag was still available from the treatments earlier that day, I compared the product labelling. The previous supplier's label listed a total of 4,000 milligrams, a total volume of 105.26 millilitres and a gemcitabine concentration of 38 milligrams per millilitre. On the other hand, the Marchese label indicated only four grams in 100 millilitres. I also noted that the electronic preparation worksheet used to calculate the dose used was 38 milligrams per millilitre, which was the Baxter final concentration.

With these important details outstanding, I was unclear whether the final concentration was 40 milligrams per millilitre, 38 milligrams per millilitre or otherwise. I consulted with our on-site DRCC pharmacist by phone regarding the bag labelling, the concentration and whether the electronic worksheet had the correct concentration for the Marchese gemcitabine bag. The pharmacist instructed me to hold treatment until hearing back from them.

I also consulted with Judy, our senior pharmacy assistant, regarding the concentration of the Marchese bag. The on-site pharmacist came to the pharmacy, as Judy, our senior assistant, went to place a call to Marchese for

clarification. You will hear about that call in her testimony.

The on-site pharmacist provided instruction to dispense the product. The medication was then released from the pharmacy to nursing for administration to the patient. Our manager of cancer care was in the area, and Judy made her aware of the potential issue and further inquiries. During her testimony, my colleague Judy will outline the steps she and I undertook with Marchese to make further inquiries. Since the incident, I participated in an in-depth interview with Dr. Thiessen.

Now I will be pleased to take any questions.

The Chair (Mr. Ernie Hardeman): Thank you very much. If that's all in your presentation, we will start the questioning, so we'll go to—

Mr. Jeff Yurek: Judy's next, isn't she? Oh, sorry.

The Chair (Mr. Ernie Hardeman): No, the witnesses will be done one at a time.

Mr. Jeff Yurek: Okay.

The Chair (Mr. Ernie Hardeman): And so the questions will start with the official opposition.

Mr. Jeff Yurek: Sorry about that, Chair.

The Chair (Mr. Ernie Hardeman): Thank you.

Mr. Jeff Yurek: Thanks, Craig, very much for coming in, and thank you for the job you've done at the hospital in finding that error in the bag. I worked with a lot of pharmacy assistants and technicians, and I know how difficult a job it can be for you sometimes, but being alert and on the ball bodes well for you and it bodes well for the hospital. Congratulations and thank you very much.

Mr. Craig Woudsma: Thank you.

Mr. Jeff Yurek: And congratulations on working towards your regulation technician; that's a long process too—

Mr. Craig Woudsma: It really is, yes.

Mr. Jeff Yurek: Good luck on that exam coming up.

My question is, just in general with regards to Medbuy, do you know of or is there a policy at the hospital that if you're unhappy with the product you're receiving, you could contact Medbuy and say, "Look, I don't like what I'm receiving." Do you know of a process, or are you involved in one?

Mr. Craig Woudsma: I'm not involved with Medbuy at all. That's kind of a removed process. It's above where we are, so I don't really know.

Mr. Jeff Yurek: So with that product, you just go to the senior pharmacy assistant or the pharmacist, and then they would take it further?

Mr. Craig Woudsma: Exactly.

Mr. Jeff Yurek: Okay. You know what my question's going to be, Judy, when you're up, right?

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So the Baxter product wasn't refrigerated. Have you checked if the product needs to be refrigerated at all? Like is that just a—

Mr. Craig Woudsma: In the moment, the question of whether it needed to be refrigerated or not came up. Then

we noticed on the label that it did say for the Marchese bag to be kept refrigerated.

Mr. Jeff Yurek: Have you ever checked into that, into the literature to see if that was actually a necessity or not?

Mr. Craig Woudsma: Not up until this point, no.

Mr. Jeff Yurek: So you had no problem with the Baxter bag you had been using for the last year. Then when you switched over to the new bag, that's when you noticed the problem.

Mr. Craig Woudsma: That's right.

Mr. Jeff Yurek: Could you explain the worksheet that you work with?

Mr. Craig Woudsma: Certainly. It's an electronic worksheet that is the result of the physician doing a computerized order entry. Then it goes to the pharmacist for checking. When it comes to us in the pharmacy, it has the patient's name, all their pertinent information—height, weight, BSA, that kind of thing. It has the regime that they're taking, the drugs specific to that regime. Then there's a breakdown of milligrams that the patient will be receiving, then an associated volume and then areas for doing a written check.

Mr. Jeff Yurek: And do you have someone check the work that you do?

Mr. Craig Woudsma: Our quality assurance process involves two assistants.

Mr. Jeff Yurek: Right.

Mr. Craig Woudsma: One is inside the biological safety cabinet actually doing the admixing. Then there's someone on the outside of the cabinet doing checks as well.

Mr. Jeff Yurek: So explain to me the process of making the bag, at the end of the day. Do you put a new label on a new bag? Is it patient-specific when you're done? Just go through the whole—

Mr. Craig Woudsma: I can go through the whole thing. The doctor does the order entry. It goes to the pharmacist for checking. We get a label, and then the pharmacist passes us a copy of the computer-generated worksheet.

From there, the assistant on the outside of the biological safety cabinet takes the correct bag, the drug, and makes sure the line for the bag is primed. It gets passed in, labelled, to the pharmacy assistant inside the hood, as well as the drug and associated items that they're going to need to withdraw the medication and then admix it to the bag. The assistant inside the hood does a non-verbal check of everything, and the assistant on the other side of the hood also does a non-verbal check of everything. Then, there's a final verbal check at the end before the bag gets admixed, so the drug gets added to the bag. From that point, it gets wiped down, placed in a chemo transport bag and then, in our case, gets put into a pass-through window, which is where nursing retrieves the medication.

Mr. Jeff Yurek: How has your workflow been since the incident? I imagine you're doing more compounding now than you were beforehand.

Mr. Craig Woudsma: Previously, yes. But before the medications came already mixed, we were doing everything by hand, as it were. We were mixing the vials etc., so it really hasn't impacted our workflow at all.

Mr. Jeff Yurek: Have there been any problems with the compounding in the hospital at all?

Mr. Craig Woudsma: No.

Mr. Jeff Yurek: You had no problems. I will pass it on.

Mrs. Christine Elliott: Good afternoon, Mr. Woudsma. I'd really also like to thank you very much, you and Ms. Turner, for coming forward to the committee. I know this has been a very difficult time for all of you, but I think it's really critical that we hear from you about what actually happened. Contrary to some of the news reports we've heard which suggested that you compared the actual volumes in the bags, it sounds to me that you were first alerted by the fact that the Marchese product, the new product, needed to be refrigerated, and then you investigated further. Is that fair to say?

Mr. Craig Woudsma: That would be correct.

Mrs. Christine Elliott: Okay. You did refer to the labelling on a Baxter bag. Was that an empty bag that you looked at or was that a filled bag?

Mr. Craig Woudsma: That was a bag that had a remainder of medication in it that wasn't sufficient to administer to a patient. So it was kind of just a leftover. It was the transition from the last of that stock to the new Marchese stock, so it was handy that we just had it on hand.

Mrs. Christine Elliott: But did you consider that the Baxter product labelling was ever a problem, or was it always very understandable to you about what the product contained?

Mr. Craig Woudsma: It was quite clear.

Mrs. Christine Elliott: Okay. And it was very apparent from the Marchese bag that it wasn't clear, is that correct?

Mr. Craig Woudsma: It was vague. So it just kind of begged the question.

Mrs. Christine Elliott: Okay. Is it very common for you to dispense a whole bag to one particular patient, or is it more common to use one bag for more than one particular use per patient?

Mr. Craig Woudsma: In this case, the medications are patient-specific and regime-specific. There are a whole bunch of variations just on the medication itself. In this case, with the gemcitabine, you give partial doses out of the larger stock bag.

Mrs. Christine Elliott: Would you ever have dispensed a whole bag to one patient?

Mr. Craig Woudsma: I don't know.

Mrs. Christine Elliott: Have you ever?

Mr. Craig Woudsma: I haven't, but I couldn't say that that couldn't happen. That's beyond my scope of practice.

Mrs. Christine Elliott: Could you tell us a little more about the conversation, as you knew it? I don't think you were the one who spoke directly with the Marchese rep,

but can you just tell us what you heard about that conversation?

Mr. Craig Woudsma: There were several conversations that happened. I was party to one conversation at the end when a pharmacist called us back, and it was involving their admix process for preparing the bag, which raised more questions.

Mrs. Christine Elliott: Because it was pretty clear that they thought the entire bag was going to be used for one patient.

Mr. Craig Woudsma: It was pretty clear, yes.

Mrs. Christine Elliott: And the pharmacist who actually allowed the dosage to be administered to the patient, notwithstanding some concern about the concentration and the volumes—do you know why the pharmacist made that decision to dispense the product?

Mr. Craig Woudsma: Again, that's above my scope of practice.

Mrs. Christine Elliott: You weren't involved in that, then?

Mr. Craig Woudsma: No, I was not involved in that decision.

Mrs. Christine Elliott: I think that's it. Thank you very much.

The Chair (Mr. Ernie Hardeman): Okay. The NDP: Ms. Gélinas.

M^{me} France Gélinas: It's a pleasure to meet you, Mr. Woudsma. I too want to congratulate you for your keen eye and basically for doing your job extremely well. I hope many other people took the occasion to thank you and to congratulate you. We're really proud of what you have done. I know that coming here doesn't seem like a reward, and I'm not going to pretend. We'll do our best to make that brief and let you go back to your work that you seem to be really enjoying. I think you've made a wise choice.

My first question follows up on the one you've heard. Right now, the pharmacy assistants are doing the whole preparation of gemcitabine. You go from the powder to the mixing to the concentration—all of this in-house.

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: Is this something you had ever done before?

Mr. Craig Woudsma: Yes, it was something we had done before.

M^{me} France Gélinas: And then you went to Baxter, then you went to Marchese and then you came back to that?

Mr. Craig Woudsma: That's correct.

M^{me} France Gélinas: And were you worried about having to mix those drugs?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: No? You feel you're competent to do this?

Mr. Craig Woudsma: Absolutely, yes.

M^{me} France Gélinas: And can you see any reason why you didn't simply continue to mix those drugs the whole time?

Mr. Craig Woudsma: I couldn't really speak to that. It was a decision that was made above us working in the pharmacy.

M^{me} France Gélinas: Had you ever asked for those drugs to not be mixed in-house?

Mr. Craig Woudsma: No. No, I didn't.

M^{me} France Gélinas: You didn't feel worried about it; you didn't feel it was too hard to handle or took too much time or anything of the sort?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: You feel pretty competent about it all. You've convinced me.

You said that now you're mixing it all, from the powder form all the way to the delivering it to the nurse in-house. Is this a bigger workload than you used to have? Are you guys working longer hours or are other people being brought in?

Mr. Craig Woudsma: No. It hasn't affected our workflow at all. It's a readjustment of what our daily process was. Every day we prepare for the next day, so that just became part of that process. Again, it was something, like I said, we had done previously. It hasn't been a problem.

M^{me} France Gélinas: It hasn't changed the number of staff, the number of hours or anything like this?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: Okay. I want to come back—he knows pharmacy way better than I. I also noted that the electronic preparation worksheet used to calculate the dose used 38 milligrams per millilitre, which was the Baxter final concentration.

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: Who had written that down, the 38 milligrams per millilitre?

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Mr. Craig Woudsma: I don't know. That gets pre-programmed in, and I'm not sure who was actually responsible for that.

M^{me} France Gélinas: So the physician had given you—the number of milligrams was on the prescription, as to how many milligrams were going to be delivered to that patient?

Mr. Craig Woudsma: That's right.

M^{me} France Gélinas: And you were to do the calculations from the concentration that you saw, and then you were to calculate it back how many you were to draw?

Mr. Craig Woudsma: Well, the calculation is already done. The worksheet indicates the milligrams the patient is supposed to receive, as well as the volume that is associated with that, and from that you can infer the concentration that they're using. That was, in that case, 38 milligrams per millilitre.

M^{me} France Gélinas: All right. So the 38 milligrams per millilitre that were on your worksheet, basically you had no way of knowing if this is what was in the bag? Somebody had taken for granted that this is what was in the bag?

Mr. Craig Woudsma: I can't speak to that. All I can say is that we caught it with our QA process and

identified that there was an inconsistency on some level that needed clarification.

M^{me} France Gélinas: Okay. I'm still curious as to, in the process of putting those electronic worksheets together, who works on that?

Mr. Craig Woudsma: I don't know.

M^{me} France Gélinas: It just comes to you; it just comes?

Mr. Craig Woudsma: Exactly. It comes as a program, and that's kind of just what we go on.

M^{me} France Gélinas: And this is where you start to work.

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: Okay. Sounds good.

You did say that you "consulted with our on-site DRCC pharmacist by phone regarding the bag labelling, the concentration and whether the electronic worksheet had the correct concentration" for the Marchese bag. Who was that pharmacist?

Mr. Craig Woudsma: I'm prepared to provide that if we could provide that to the Clerk afterwards.

M^{me} France Gélinas: Sure. No problem. You can provide it to the Clerk after.

From the time you were at the hospital, do you know how long this drug had been prepared on-site versus how long it had been outsourced, either to Baxter or to Marchese?

Mr. Craig Woudsma: From my perspective, when I started in oncology in 2011, in the spring of 2011, at that point we were compounding them by hand. It was shortly thereafter that they were brought in premixed. Like I said, I wasn't part of that decision or anything like that.

M^{me} France Gélinas: It just happened.

Mr. Craig Woudsma: It just happened.

M^{me} France Gélinas: Do a lot of drugs get outsourced like this?

Mr. Craig Woudsma: Not in the oncology pharmacy.

M^{me} France Gélinas: No? Are the two drugs that we have been dealing with the only two that you know of, or are there more?

Mr. Craig Woudsma: No. In our clinic, there was gemcitabine, the cyclophosphamide, as well as pamidronates and fluorouracil infusers.

M^{me} France Gélinas: That are off-site.

Mr. Craig Woudsma: That were produced off-site, yes.

M^{me} France Gélinas: Do you know if the pharmacy at your hospital and your cancer treatment centre have ever done it in-house?

Mr. Craig Woudsma: Absolutely. We do those in-house as well, subsequently, and that was done beforehand as well. They were made in-house.

M^{me} France Gélinas: Are you now making all of them in-house again?

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: You are, eh? The outsourcing was fun but really not that much fun. All right.

When we look at the website for Medbuy—Medbuy are actually the people who help with the outsourcing—

their website is really clear: They are there to save money. Do you feel that this is why some of the drugs had been outsourced, in an effort to save money?

Mr. Craig Woudsma: I couldn't say. I don't know.

M^{me} France Gélinas: You don't know. But as far as the staff schedule, number of hours, none of this had changed?

Mr. Craig Woudsma: No. Nothing like that was affected.

M^{me} France Gélinas: And now that you have this extra workload for those four drugs, nothing has changed either?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: And do you know if any of your co-workers are worried about preparing those drugs, like they liked it better when it came already premixed? Are you the only one who feels comfortable, or all of you?

Mr. Craig Woudsma: I can't speak to the opinions of my colleagues, but it's a process that we used to do, and it's a process that we've been doing now for a little bit of time. We're all extremely well trained and competent in what we do, so I feel confident.

M^{me} France Gélinas: Everybody is comfortable with the process.

Did you want to go?

Ms. Cindy Forster: Keep going. You're on a roll.

M^{me} France Gélinas: Okay. The process of outsourcing: Has this ever been discussed? I take it you have department meetings?

Mr. Craig Woudsma: Those are high-level conversations that don't happen with the regular pharmacy staff.

M^{me} France Gélinas: Okay. But do you have department meetings at your level? Do you ever meet as a group?

Mr. Craig Woudsma: Yes, absolutely.

M^{me} France Gélinas: And were there ever worries raised at your level that you didn't want to prepare some of the drugs, that you didn't feel comfortable preparing some of the drugs?

Mr. Craig Woudsma: No. Not that I'm aware of, no.

M^{me} France Gélinas: It never came from you guys? This was never an issue?

Mr. Craig Woudsma: No.

M^{me} France Gélinas: When it became known and you started to talk to people, why was it that you were so reluctant to speak?

Mr. Craig Woudsma: I'll speak in my case specifically. What we do is for patient care. We're not looking for glory or anything like that. What we do is kind of the same thing, day in, day out, and we're there for the patients. We didn't want to add to the spectacle that it kind of became.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes your 10 minutes. It goes a lot quicker than the 20.

M^{me} France Gélinas: All right, then.

The Chair (Mr. Ernie Hardeman): Thank you. With that, then, Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair, and on behalf of the government, we would like to thank you so very much for being so alert and on top of the situation, and questioning and doing everything right, so our congratulations as well.

My colleague has been focusing on the outsourcing and what has happened since you've brought the process back in-house. You've been working at Peterborough since 2007. When outsourcing was started, was there any decrease in your normal complement of assistants or any changes?

Mr. Craig Woudsma: Well, I started in 2009. I just want to clarify.

Ms. Helena Jaczek: Okay.

Mr. Craig Woudsma: Not that I'm aware of. There hasn't been a decrease from the outsourcing at all, no.

Ms. Helena Jaczek: So in 2009, you had the same complement assigned to the cancer clinic as you do now?

Mr. Craig Woudsma: At the time when I started—I didn't actually start in the cancer clinic until 2011, and I don't recall the complement of people who were in cancer care at the time, but when I was brought on, nothing has changed since that point.

Ms. Helena Jaczek: Okay. And when you were brought on in 2011, you were compounding yourself?

Mr. Craig Woudsma: Yes.

Ms. Helena Jaczek: Yes. Okay. I just wanted to make that clear. So there was no real change due to outsourcing that impacted the staff complement assigned to cancer care.

Mr. Craig Woudsma: No.

Ms. Helena Jaczek: Thank you. You were originally certified through the Ontario College of Pharmacists, so you are a pharmacy assistant going through training to become a pharmacy technician.

Mr. Craig Woudsma: Yes.

Ms. Helena Jaczek: Could you just tell us what the difference in scope of practice will be once you're through your training?

Mr. Craig Woudsma: Okay. The previous process was certification through OCP, the Ontario College of Pharmacists, and then subsequently legislation came out that allowed for the regulated pharmacy technician title, and it became a protected title. So we, assistants, were given the opportunity to do bridging programs to achieve a regulated status, and that is making it kind of an even playing field. So when you say a pharmacy technician, you know that they've gone through a certain process and they'll have the same competencies. It's different in every jurisdiction as to the exact rules, and they're kind of always in flux, so we're always checking the OCP website to see exactly how things have changed.

Ms. Helena Jaczek: But you're expecting to have essentially the same type of work?

Mr. Craig Woudsma: In the hospital setting, again, there are differences if you were in a community-based practice versus a hospital-based practice, and in the hospital it's kind of a continuing of duties, but there's an

added level of responsibility and accountability coming from a legal perspective.

Ms. Helena Jaczek: And has the hospital been encouraging you to upgrade, or how is that working?

Mr. Craig Woudsma: It was made mandatory to achieve it by March 2014, and they've provided financial compensation to achieve that.

Ms. Helena Jaczek: Okay. Thank you. In terms of this electronic preparation worksheet—I guess we're really all concentrating on this. So you really are not clear who prepares that. I mean, is it the physician, the pharmacist? Would you have any idea?

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Mr. Craig Woudsma: Well, it's the physician who makes the order and the pharmacist who checks the order, but the actual programming of the concentration of the medication, I don't know. I know values are put in by the doctor for what they want to achieve for the patient, but the broader scope of how the program was put together, I'm not aware of.

Ms. Helena Jaczek: I think we're all kind of making an assumption that the 38 milligrams per millilitre was used because everybody knew that's what Baxter provided. I mean, it just seems logical that Baxter was always 38 milligrams per millilitre, and so nobody, other than you, was necessarily aware that the product suddenly was going to say four grams in 100 millilitres.

I'm sort of wondering if the worksheet had actually had 40 milligrams per millilitre, would you have questioned the concentration in the Marchese bag?

Mr. Craig Woudsma: I don't want to, kind of, conjecture. The labelling raised questions on its own, independent from the concentration on the worksheet, and I think that speaks for itself.

Ms. Helena Jaczek: That's what started it for you.

Mr. Craig Woudsma: Yes.

Ms. Helena Jaczek: Okay, we're clear on that.

Again, this relationship—you have an on-site DRCC pharmacist and then there is an on-site pharmacist. I'm wondering, you would normally report—and this is why you consulted with the DRCC pharmacist, because you're the cancer piece of the pharmacy. You got conflicting views on administration—

Mr. Craig Woudsma: The DRCC on-site pharmacist is the on-site pharmacist.

Ms. Helena Jaczek: Oh, it's the same pharmacist.

Mr. Craig Woudsma: Yes.

Ms. Helena Jaczek: Again, then, I'm a little unclear. The first instruction was hold treatment and then that same individual said, "Go ahead and administer."

Mr. Craig Woudsma: That's correct.

Ms. Helena Jaczek: Okay, I got that.

Your hospital pharmacy's relationship with the Durham Regional Cancer Centre is essentially very direct. I mean, the DRCC on-site pharmacist may be physically located in Peterborough but is essentially the responsible pharmacist for the administration of chemotherapy. Is that correct?

Mr. Craig Woudsma: The DRCC pharmacist who is on site is responsible for checking the orders that come from the physicians that we have there in the clinic.

Ms. Helena Jaczek: Okay. You mentioned your in-depth interview with Dr. Thiessen. Can you share what the conversation was about?

Mr. Craig Woudsma: It was an in-depth look at the exact events of that day, kind of from every step. He had some very pointed questions, and we answered them completely openly.

Ms. Helena Jaczek: And so another tipoff, apart from this discrepancy between the electronic worksheet and the concentration, was this issue of refrigeration or not. Baxter didn't have to be refrigerated, and Marchese did. Would you be aware of why that would be? I mean, essentially you've got the same products in the mixture.

Mr. Craig Woudsma: I couldn't say.

Ms. Helena Jaczek: Okay.

Mr. Craig Woudsma: They could have used a different product to make it, or whatnot. It's hard for us to say there in the pharmacy. All we can do is question it.

Ms. Helena Jaczek: I think that we've covered as much as we need to. Thank you very much.

Mr. Craig Woudsma: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Elliott?

Mrs. Christine Elliott: Thank you. I just have a few follow-up questions.

Mr. Woudsma, were you the first person to use the new product. Had everybody else that day been using the remainder of the Baxter product?

Mr. Craig Woudsma: That is correct. This was the first patient to use stock from Marchese.

Mrs. Christine Elliott: So you were the first assistant to notice the different products and to be alerted to the fact that there were some differences between the two.

Mr. Craig Woudsma: Well, we were all aware that a new supplier was being used instead of Baxter, but myself and my colleague were the first ones to encounter having to use this medication specifically.

Mrs. Christine Elliott: And this is your colleague who's going to come at a later time, or wasn't able to come today?

Mr. Craig Woudsma: Wasn't able to come today.

Mrs. Christine Elliott: Okay. Did anybody else notice it? Any of the other assistants, did they notice a concern when the product came in and the fact that it had to be refrigerated? Were there questions that were being asked about the new product?

Mr. Craig Woudsma: I can't speculate. I think there were some questions about stability because it was a different supplier, so there might be variations. But I can't speak to that because I wasn't involved in any process with that. It hadn't gone through our rigorous QA process that we use when administering, so that was the portion—that's how it got picked up.

Mrs. Christine Elliott: Thank you very much.

Mr. Craig Woudsma: Thanks.

The Chair (Mr. Ernie Hardeman): Thank you. Did you have another couple of questions? We have a little mix-up here with my time.

M^{me} France Gélinas: Thank you, Mr. Chair. Just in follow-up to Dr. Jaczek, you said that you participated in a meeting with Dr. Thiessen. Who else was there at the meeting with you and how long did the meeting last?

Mr. Craig Woudsma: At the time, if I remember correctly, there was myself, Judy and our fellow colleague who is not with us today; there was Dr. Thiessen, as well as the hospital's lawyer. I can't remember—I believe Margot DaCosta was there; she's one of our directors. I can't recall. It lasted for about an hour.

M^{me} France Gélinas: For about an hour?

Mr. Craig Woudsma: Yes.

M^{me} France Gélinas: Did you have any preparation before coming here? Did anybody talk to you about coming to Queen's Park?

Mr. Craig Woudsma: We had some preparation insofar as what we were going to say and what we could anticipate because it's a rather unique situation for us.

M^{me} France Gélinas: Who helped prepare you?

Mr. Craig Woudsma: It was a combination of staff at the PRHC executive level who helped with that.

M^{me} France Gélinas: Could you name them for me?

Mr. Craig Woudsma: Certainly. Dr. McLaughlin, Arnel Schiratti, Brenda Weir. As well, our manager was sitting there at the time, Karyn Perry.

M^{me} France Gélinas: And what did they say?

Mr. Craig Woudsma: It was kind of just going through what our statements would entail and the kind of questions that we could anticipate. Like I said, it being kind of a unique situation, we're not—

M^{me} France Gélinas: Who wrote your statement for you?

Mr. Craig Woudsma: It was a collaborative process of us indicating our information as well as a detailed report of the events that had transpired. That kind of came together at that.

M^{me} France Gélinas: And who was part of that team that put it together?

Mr. Craig Woudsma: I believe Arnel Schiratti—he's our communications—and I believe his assistant as well. I don't know her name, I'm sorry.

The Chair (Mr. Ernie Hardeman): Okay. It's your last question; make it a good one.

M^{me} France Gélinas: Oh no. The issue of whether the drugs were prepared in concentration-specific or non-concentration-specific has been an issue here. As far as your understanding of the drug that you were going to draw from, was it your understanding that this drug was supposed to be concentration-specific?

Mr. Craig Woudsma: All our drugs are concentration-specific based on the dose and the patient's specific information.

M^{me} France Gélinas: Okay. So—

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Jaczek?

Ms. Helena Jaczek: Well, I think it's probably a follow-up. When you saw on the Marchese label "4 g in 100 mL," that is essentially a concentration, is it not?

Mr. Craig Woudsma: It leads you to believe that the concentration, perhaps, would be 40 milligrams per millilitre, but it doesn't explicitly say that, so we questioned it.

Ms. Helena Jaczek: So did you then—because I don't see it in your presentation—actually take the bag and measure the total cc's or millilitres in the bag?

Mr. Craig Woudsma: No. That wouldn't be something that we would do because that would be manipulating the solution, and we try to keep manipulations down to a minimum for sterility purposes.

Ms. Helena Jaczek: Was there ever any check done on that bag to find out what the actual concentration was?

Mr. Craig Woudsma: No. What was done was a question to the company to provide clarification as to what the exact concentration was.

Ms. Helena Jaczek: And then what was that communication back to you? What did they say?

Mr. Craig Woudsma: In the conversation that I was a party to, it was reiterated that the four grams in 100 millilitres was sufficient and the concentration wasn't pertinent. Then we indicated the concentration would be pertinent, given their method of preparation, and then they said they would follow up.

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Ms. Helena Jaczek: Because I think we've read somewhere that the actual volume was 107 millilitres. I'm wondering where that came from.

Mr. Craig Woudsma: Right. I think that speaks to overfill—

Ms. Helena Jaczek: Right.

Mr. Craig Woudsma: —and there's overfill in some bags, so that raises a question.

Ms. Helena Jaczek: So when you were party to the conversation with Marchese, did they allow as much, that there could be overfill, or did they maintain there was 100 millilitres in the bag?

Mr. Craig Woudsma: They maintained there was four grams in the bag and that the overfill wasn't pertinent because the concentration wasn't pertinent.

Ms. Helena Jaczek: I see. Okay. Thank you.

I think we are satisfied at this point. I think we're probably out of time, as well.

Interjection.

Ms. Helena Jaczek: How much time do we have left?

The Chair (Mr. Ernie Hardeman): You have another minute left.

Ms. Helena Jaczek: Okay. I think we'll just conclude by saying thank you again, and good luck to you in the future.

Mr. Craig Woudsma: Thank you.

The Chair (Mr. Ernie Hardeman): Okay, thank you. You have one question, Mr. Yurek?

Mr. Jeff Yurek: I have two questions.

The Chair (Mr. Ernie Hardeman): Make them quick; you don't have that much time.

Mr. Jeff Yurek: I just perked up when you said you were in a conversation with someone who said the concentration wasn't pertinent in this case?

Mr. Craig Woudsma: That's correct.

Mr. Jeff Yurek: Who were you talking to at that point?

Mr. Craig Woudsma: A pharmacist at Marchese had called the pharmacy and had discussed their method of preparation. We had reiterated that overfill was an issue in the concentration—is an issue. The response was quite clearly that the concentration didn't matter; there was the understanding on their part that the full four grams was administered to the patient.

Mr. Jeff Yurek: At that point, they thought—

Mr. Craig Woudsma: At that point.

Mr. Jeff Yurek: Their idea was that the whole bag was given?

Mr. Craig Woudsma: That's right.

Mr. Jeff Yurek: Okay.

The Chair (Mr. Ernie Hardeman): Thank you very much.

Mr. Jeff Yurek: Oh, do you still use empty bags? Do you fill from empty bags now, or do you withdraw solution and fill in?

Mr. Craig Woudsma: What we do is, we—sorry, do I respond?

The Chair (Mr. Ernie Hardeman): Yes, go ahead and answer the question.

Mr. Craig Woudsma: With the medications that we have prepared in vials, we withdraw a specific amount of fluid and, based on stability and the whole range of information for that drug specifically, we further dilute it. There are some medications that are administered through direct subcutaneous access, but by and large, the medications all require further dilution.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes that presentation.

MS. JUDY TURNER

The Chair (Mr. Ernie Hardeman): We will now start the second presentation this afternoon. Judy, as with the previous one, you have 10 minutes to make your presentation, and then we'll have questions from each party. This time, the questioning will start with the third party.

Ms. Judy Turner: Thank you, Mr. Chair, and good afternoon, members of the legislative committee. As my colleague Craig said, I'm the senior pharmacy assistant in the cancer clinic.

I began my training and career in health care as a registered nursing assistant for 10 years at the Peterborough Civic Hospital. I went on to receive further pharmacy-specific training at Humber College. At the beginning of my pharmacy career, I worked for four years in the main pharmacy, and have spent the last 15 years specializing in the oncology pharmacy. I am a code brown hazardous materials spill trainer, and assisted in

all training and certification for hospital staff at the Peterborough Regional Health Centre.

I sit on the Central East regional pharmacy committee, where we developed a new safe handling manual for chemotherapy agents. I was also proud to represent PRHC at a safe handling seminar in Colorado. I have completed all of my pharmacy technician registration exams and am awaiting notification of the final stage.

In my testimony, I wish to focus on the events of the afternoon of March 20, 2013, beginning at 14:30, when I became involved in further exploration and investigation with Craig.

Upon comparing the bags, I noted that the Marchese bag was mixed in a Hospira bag, which has a known approximate overfill of seven millilitres. It was not clear from the labelling on the Marchese bag if the overfill had been included to determine the final concentration.

At 14:33, I called the pharmacist to sit in on a call to the supplier, Marchese, to seek clarification about the concentration. When I asked about the overfill and the impact on the concentration, the Marchese staff member responded that it was still four grams in 100 millilitres. They also offered to have me speak with a Marchese pharmacist. I agreed and awaited the call.

A Marchese pharmacist contacted us shortly thereafter and advised us that the final concentration would not change due to the overfill because the entire contents of the bag would be administered to the patient. We explained the process for our dose delivery, that the patient would in fact not receive the entire contents of the bag, and that the entire four grams would therefore not be given to a patient. The Marchese pharmacist stated that they would need to investigate further and get back to me.

At 15:30, I made the manager of our cancer clinic aware of a potential concentration issue.

Further to the direction from the DRCC pharmacy, PRHC immediately discontinued use, and the supply of gemcitabine was quarantined in the PRHC pharmacy.

I would later receive an email from Marchese indicating that they were working on a solution and would provide follow-up.

Since that incident, I've participated in an in-depth interview with Dr. Thiessen.

This concludes my remarks about the events of March 20, 2013. However, I want to close by making a few brief comments about our team.

I'm very proud of the group of professionals I have the privilege of working alongside. I also wish to recognize the exceptional team of physicians, nurses, pharmacists and other health care professionals who help our patients get the care and support they need in their personal battle against cancer.

Finally, on behalf of everyone at PRHC, we would like to publicly acknowledge and thank everyone at Cancer Care Ontario, the Durham Regional Cancer Centre and Lakeridge Health who have been behind PRHC every step of the way.

Without their support in the development of our cancer services at PRHC, cancer patients from Peter-

borough and beyond would have little choice but to travel to Oshawa for care multiple times weekly in all types of weather.

Soon we will be complementing our existing services with the opening of the Norm and Jessie Dysart radiation suite at PRHC. We're looking forward to that day in June, when patients requiring radiation treatment will be able to remain closer to home.

Thank you, and I'd be happy to take questions.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. We will start this round with the third party.

Ms. Cindy Forster: Thank you. Thanks very much for being here. In your presentation, you talked about, "I later received an email from Marchese indicating that they were working on a solution and would provide follow-up." Did they follow up?

Ms. Judy Turner: No, they didn't.

Ms. Cindy Forster: Thank you. Are front-line staff in your pharmacy ever asked to review, assess or evaluate products?

Ms. Judy Turner: No, they're not.

Ms. Cindy Forster: They're not. Okay.

Can you expand upon the issue of refrigeration? I'm still not quite clear on that. Two particular medications that were sourced through Marchese you formerly got from Baxter. The Baxter sourcing didn't require refrigeration, but Marchese did. Did you do any kind of investigation into why the differences?

Ms. Judy Turner: That would be beyond my scope.

Ms. Cindy Forster: Someone indicated in their presentation that a pharmacist directed the medication as it was labelled, the four grams in 100 millilitres to be administered. I'm assuming that this was based on the specific dose for the patient and not to actually administer the entire bag.

Ms. Judy Turner: Can you repeat the question?

Ms. Cindy Forster: Somewhere in somebody's presentation, they had checked with a pharmacist, who said to go ahead and administer that first bag that was in question. So I'm assuming that that direction was based on the specific dose from your electronic order sheet and not to administer the entire four grams.

Ms. Judy Turner: Just a clarification: So—

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The Chair (Mr. Ernie Hardeman): Excuse me. Ms. Forster, could you move your mike closer? Ms. Turner too. Speak directly into the microphone.

Ms. Judy Turner: Is that better?

The Chair (Mr. Ernie Hardeman): Thank you.

Ms. Judy Turner: Your question is, did the pharmacist direct the assistants to administer—

Ms. Cindy Forster: —a dosage that was on your electronic worksheet.

Ms. Judy Turner: Yes, right, as opposed to the full bag.

Ms. Cindy Forster: As opposed to the full bag. Okay.

Now you're mixing the medications in-house again. I wasn't quite clear, with the answer that went to Mr.

Yurek, about whether or not you use an empty bag, mix your medications, fill that bag and then use that bag for multi-dose, or whether you're using a bag which in one situation has 107 millilitres in it generally, and mixing your drug and then adding it to the bag.

Ms. Judy Turner: On our bags that contain our drugs, once they're put into the bag, on our label it will tell you a total volume.

Ms. Cindy Forster: Right. But how do you know what the volume is in that particular bag, if the bags have overfill?

Ms. Judy Turner: Right. We have a chart, and the overfill is listed on the chart, so it would be on the label.

Ms. Cindy Forster: So every bag has the same overfill.

Ms. Judy Turner: Depending on the company, it's plus or minus.

Ms. Cindy Forster: Okay. Today, when you are actually doing your own mixing of these drugs, are they still multi-use, multi-patient-use bags that you're mixing, or are they individual patient doses?

Ms. Judy Turner: They're individual.

Ms. Cindy Forster: They're individual patient—

Ms. Judy Turner: —doses.

Ms. Cindy Forster: —doses. Was Marchese preparing any other medications, other than those two chemo agents, for your pharmacy?

Ms. Judy Turner: Yes. They prepared pamidronate and the fluorouracil.

Ms. Cindy Forster: Which are also cancer agents?

Ms. Judy Turner: Yes.

Ms. Cindy Forster: Any other drugs beyond those, that you're aware of?

Ms. Judy Turner: Not that I'm aware of.

Ms. Cindy Forster: Okay. Thank you.

The Chair (Mr. Ernie Hardeman): Ms. Gélinas.

M^{me} France Gélinas: Since then, aside from the bag that alerted you, did you go and check on the other drugs that you were receiving from Marchese? Or you simply refused to use them?

Ms. Judy Turner: Everything was quarantined when we had the directive from the DRCC.

M^{me} France Gélinas: Okay. In your testimony, you say that you called Marchese. "When I asked about the overfill and the impact on the concentration, the Marchese staff member responded that it was still four grams in 100." Who was that staff at Marchese who said that?

Ms. Judy Turner: Her name was Bobbi Young.

M^{me} France Gélinas: Okay—oh, my pen just died—Bobbi Young. Then, "A Marchese pharmacist contacted us shortly thereafter." Who was that pharmacist?

Ms. Judy Turner: I only have the spelling of her first name, and I'm not even sure if the spelling is correct.

M^{me} France Gélinas: Try me.

Ms. Judy Turner: It's K-A-W-T-H-E-R.

M^{me} France Gélinas: Basically, she introduced herself by her first name, and she's the one who told you

that the drugs—the whole bag was going to be used on a single patient.

Ms. Judy Turner: That's correct.

M^{me} France Gélinas: Okay. You have been at the pharmacy for 11 years—

Ms. Judy Turner: Fifteen.

M^{me} France Gélinas: Even longer; for 15 years. I missed four years, somehow. Would you say that in your time in pharmacy—was there a time where all the drugs were done in-house, or did you always outsource?

Ms. Judy Turner: There was a time when they were all done in-house.

M^{me} France Gélinas: Do you have any supervision responsibility as the senior—

Ms. Judy Turner: Not supervision responsibility, no.

M^{me} France Gélinas: No? So what does it mean to be a senior assistant?

Ms. Judy Turner: In my role, I do billing, I do certification for the assistants coming into our cancer clinic, I sit on committees and I work inside the preparation room two days a week.

M^{me} France Gélinas: All right. In the committees that you sit on, were you ever part of discussion as to—have you ever requested that some drugs be outsourced?

Ms. Judy Turner: No.

M^{me} France Gélinas: You've never requested that. Have you ever heard anybody else at those committees that talks about the need to outsource?

Ms. Judy Turner: No.

M^{me} France Gélinas: Do you feel quite confident that it doesn't come from the pharmacy that drugs be outsourced, it comes from someplace else in the hospital?

Ms. Judy Turner: I'm not really sure where it comes from.

M^{me} France Gélinas: But it doesn't come from where you worked, anyway?

Ms. Judy Turner: No.

M^{me} France Gélinas: Or the committee that you're part of.

Ms. Judy Turner: No.

M^{me} France Gélinas: That's good.

I will come back to this issue of concentration-specific and non-concentration-specific: Would you say that this is something out of the ordinary for the work that you do or is it pretty basic pharmacy practice to make sure that you check concentration?

Ms. Judy Turner: In our area, it's very basic that you check concentration.

M^{me} France Gélinas: This is the way work is done all the time?

Ms. Judy Turner: Yes.

M^{me} France Gélinas: Are there other areas of pharmacy where concentration doesn't matter that much?

Ms. Judy Turner: I can't comment on that.

M^{me} France Gélinas: Because you would have seen antibiotic IV bags already prepared where you give the whole bags, no?

Ms. Judy Turner: No.

M^{me} France Gélinas: Never in your life?

Ms. Judy Turner: Not in my area.

M^{me} France Gélinas: Not in your area. Did you want to add something to this? No? Okay.

Who are some of the people that coached you before you came here?

Ms. Judy Turner: There was our communications director; there was our lawyer; Brenda Weir; and Dr. McLaughlin

M^{me} France Gélinas: What's the name of your lawyer?

Ms. Judy Turner: Kate—I'm unsure of her last name.

M^{me} France Gélinas: A good friend of yours? No?

Who prepared your written statement?

Ms. Judy Turner: We had input into it, and then the communications director.

M^{me} France Gélinas: And you felt that it reflected what you wanted to tell us?

Ms. Judy Turner: Yes.

M^{me} France Gélinas: When you talk with other people who work in pharmacy, this is being done—the outsourcing is to save money is something that we hear a lot. I mean, we go onto Medbuy's website, and it's there in black and white. This is why they exist. Would you agree that this is a motivation for the hospital to outsource drugs—to take advantage of what Medbuy is saying and to save money?

Ms. Judy Turner: I don't really have an opinion on that.

M^{me} France Gélinas: Or were you told not to have an opinion?

Ms. Judy Turner: We're not part of the Medbuy—we wouldn't be privy to those conversations.

M^{me} France Gélinas: No, but you've worked in a pharmacy for a long time.

Ms. Judy Turner: Yes.

M^{me} France Gélinas: You've seen that you're plenty capable, willing and able to prepare those drugs. This is your livelihood; this is your job. All of a sudden, your job is being outsourced, and you don't have an opinion?

Ms. Judy Turner: It would be a directive that came from up higher. It wouldn't come from the pharmacy in our institution.

M^{me} France Gélinas: But the result of it affects you. I'm not asking you what the lawyer told you to say. I'm asking you: What is your opinion of outsourcing the job that you do?

Ms. Judy Turner: I think we're there for patient safety, and that's paramount to me—if we can do it in-house safely, or it can be outsourced safely.

M^{me} France Gélinas: Do you figure it was outsourced safely?

Ms. Judy Turner: We're waiting for Dr. Thiessen's report.

M^{me} France Gélinas: Really? You don't have an opinion on that?

Ms. Judy Turner: I can't really comment on that.

M^{me} France Gélinas: Why not? Everybody else is commenting. It has been the top of the news for over a

month. It has been on the front page of the paper for six weeks. This is your livelihood; this is what you do. This is why you do it, because you want to help people. Yet, you're standing here under oath, and you don't have an opinion? There are 13 million Ontarians out there that have an opinion, and they know way less than you do.

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Ms. Judy Turner: I think if it could be outsourced safely, and save the taxpayers' money, possibly; but if it can be done in-house, then we're prepared to do that.

M^{me} France Gélinas: Then it should be done in-house.

The Chair (Mr. Ernie Hardeman): You have one more question?

M^{me} France Gélinas: I'll save it.

The Chair (Mr. Ernie Hardeman): Okay. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Ms. Turner, for your alertness in responding, and the initiative that, obviously, both of you demonstrated, especially in initiating the call with the supplier in a very timely fashion.

You've been 15 years specializing in oncology pharmacy, and that time has been in Peterborough?

Ms. Judy Turner: Yes. That's correct.

Ms. Helena Jaczek: It has. As you look back over those 15 years, in terms of the complement of pharmacy assistants that have been working in the chemotherapy area, what has happened through the years? Have you been pretty stable with the personnel or have you increased? What has been the story through the years?

Ms. Judy Turner: Historically, we've increased as our clinic has gotten busier and our patient load has gotten heavier.

Ms. Helena Jaczek: So more people, obviously, are coming closer to home, and all that good stuff.

Ms. Judy Turner: Yes, that's correct.

Ms. Helena Jaczek: When were these products outsourced to Baxter for you?

Ms. Judy Turner: Sometime in 2011, I believe.

Ms. Helena Jaczek: Okay. And during that time, you were satisfied, clearly, with the labelling. You had no anxieties with the product?

Ms. Judy Turner: No. The labels were very clear.

Ms. Helena Jaczek: And as you've told us just most recently, you don't have any personal feeling that there's inappropriate outsourcing, obviously with the proviso that patient safety is secured. Having heard that the ministry, working with the College of Pharmacists and working with Health Canada, will be putting in place oversight in terms of the College of Pharmacists being able to go into outsourcing facilities, inspect, and do their due diligence in terms of the competency of the pharmacist supervising etc., would you find that that reassures you?

Ms. Judy Turner: Yes.

Ms. Helena Jaczek: Thank you. Just to get back to this mysterious electronic paper worksheet: Are you aware of who actually prepares that, or how it gets created?

Ms. Judy Turner: It's a program somebody creates. I'm not aware of who it is.

Ms. Helena Jaczek: So in other words, your DRCC pharmacist, to your knowledge, is not involved in plugging in numbers and getting the worksheet prepared?

Ms. Judy Turner: Are you talking in terms of concentration?

Ms. Helena Jaczek: I'm talking in terms of the document that Mr. Woudsma told us had the information on it. I understand: The physician writes the order. There's a dose that is required. I guess it's puzzling that we don't seem to be able to track, from that doctor's order, how the electronic preparation worksheet gets to you.

Ms. Judy Turner: The drugs would be built in a drug dictionary. I'm not aware of who does it. Then it would flow into a physician's order; the physician would put it in. It would flow to the pharmacist. The pharmacist would check the dose, the volume and the blood work. Then it would flow to the assistants in the prep room. They would get labels and they would check their labels against the electronic order, and then the preparation takes place.

Ms. Helena Jaczek: When you called the DRCC on-site pharmacist, and said, "We've got an issue in terms of the fact that we don't know if the concentration delivered to us from Marchese is, as it always used to be with Baxter, 38 milligrams per millilitre," what was the response from the pharmacist?

Ms. Judy Turner: So, for my part, I called the DRCC pharmacist on-site and asked her to come and sit in with me on a conversation when I called Marchese. I wasn't part of that initial conversation.

Ms. Helena Jaczek: Okay. Was that Mr. Woudsma then?

Interjection.

Ms. Helena Jaczek: Yes. Okay. Then you took it sort of the next step—"Let's check this concentration." You had the conversation, and then it was you who noticed that the bag was what you knew to normally contain 107 millilitres, and that's when you had the conversation with Marchese. Then you were clearly not satisfied. When you heard that the response was that the entire bag—Marchese understood that the whole bag was going to be administered to the patient and, therefore, the patient would get four grams and you said, "No, that's not the way we do it," were you surprised at that response?

Ms. Judy Turner: I was.

Ms. Helena Jaczek: In other words, because of your experience in oncology chemotherapy, you would have also expected that the compounding facility would have the sort of knowledge that this would not be a likely dose for one patient?

Ms. Judy Turner: Right.

Ms. Helena Jaczek: So that's when the alert took place. Then immediately after that, the DRCC pharmacist said, "Hold everything. We're not using the product." Is that—

Ms. Judy Turner: Correct.

Ms. Helena Jaczek: Okay. Thank you. I think we will reserve any time for the next go-round.

The Chair (Mr. Ernie Hardeman): The official opposition: Mr. Yurek.

Mr. Jeff Yurek: Thanks, Chair. Thanks for coming in. Good job, good work, your staff.

You're a senior technician assistant?

Ms. Judy Turner: Almost there.

Mr. Jeff Yurek: Almost technician.

Ms. Judy Turner: Almost.

Mr. Jeff Yurek: You said you had—just fill us in. You're waiting for the final stage to become registered. What's that entail?

Ms. Judy Turner: Paying insurance.

Mr. Jeff Yurek: Insurance?

Ms. Judy Turner: Insurance to the college.

Mr. Jeff Yurek: Do you have any oversight of any staff, or are you just the one with the most experience?

Ms. Judy Turner: I'm the one with the most experience.

Mr. Jeff Yurek: And a lot of people rely on your thoughts and how to do stuff in the pharmacy?

Ms. Judy Turner: The assistants.

Mr. Jeff Yurek: I'm sure the pharmacists do, too.

Since you started reconstituting the two medications, the chemo drugs back in the hospital, have there been any chemo spills, any safety issues that have arisen from that?

Ms. Judy Turner: No.

Mr. Jeff Yurek: You also had a statement here—this is on page 2, I guess. You said, "We explained the process for the dose delivery"—to the Marchese pharmacist—"and that the patient would in fact not receive the entire contents of the bag, and that the entire four grams would therefore not be given to a patient." Now, this is just your thought—I want your thought on this—but wouldn't you think that Medbuy would have explicitly explained that to Marchese when awarding the contract? Does that make common sense?

Ms. Judy Turner: I would have to assume that that discussion may or may not have taken place.

Mr. Jeff Yurek: Yes. You'd think, though, it would be common sense to explain what you expect the provider to provide, wouldn't you think?

Ms. Judy Turner: I would think the expectations would be made known.

Mr. Jeff Yurek: I asked the question earlier and I said I would ask you this question: Is there a process to send a complaint to Medbuy or does it have to go through the hospital to send to Medbuy—is there a process to say, "You know, I'm not happy with the product you've procured for me"?

Ms. Judy Turner: We're not part of the procurement process.

Mr. Jeff Yurek: So if you get a faulty product, is there not—you have quality assurance there, naturally. Is there not a process that you would take your concern to?

Ms. Judy Turner: We would fill out an incident report—our internal incident reporting system.

Mr. Jeff Yurek: Okay. And where would that go?

Ms. Judy Turner: Then that would go to our med safety officer.

Mr. Jeff Yurek: And has there ever been a problem with faulty product that had to go, a response to Medbuy in the system?

Ms. Judy Turner: No.

Mr. Jeff Yurek: Not that you know of?

Ms. Judy Turner: Not that I'm aware of.

Mr. Jeff Yurek: Okay. Has the hospital had to upgrade its facility at all to handle the preparation of the chemo drugs?

Ms. Judy Turner: No.

Mr. Jeff Yurek: And the other—just one more question for this point. It's an easy one. The College of Pharmacists: You're now becoming registered with the College of Pharmacists. What are your thoughts on the College of Pharmacists actually inspecting and regulating internal hospital pharmacies?

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Ms. Judy Turner: I think it may be beneficial at some point.

Mr. Jeff Yurek: Okay.

The Chair (Mr. Ernie Hardeman): Ms. Elliott?

Mrs. Christine Elliott: Yes, thank you, Ms. Turner. I also would like to thank you for being here today and for the great work that you did with your team and with Mr. Woudsma in uncovering this problem.

You examined the bags that the Marchese product was mixed in and you discovered that it was a Hospira bag, which had a known overfill limit. Did you ever encounter that issue with the Baxter product, and what type of a bag was it packed in?

Ms. Judy Turner: The Baxter product would be prepared and then put into an empty Viaflex bag. In the conversation with Marchese, they stated that they took the fluid out of the Hospira bag to reconstitute the vials. That's how we got to the point of the overfill.

Mrs. Christine Elliott: So they didn't indicate to you that they dealt with the overfill; it was just that it contained the four milligrams in the bag, but the volume wasn't known.

Ms. Judy Turner: Correct.

Mrs. Christine Elliott: And then, can you just tell us how you got your DRCC pharmacist involved and the name of that person? Who was the pharmacist you spoke to?

Ms. Judy Turner: Can we provide that to the Clerk?

Mrs. Christine Elliott: Certainly. Is that what's normally done, Mr. Chair, the name of the pharmacist from DRCC Ms. Turner was dealing with?

The Chair (Mr. Ernie Hardeman): Yes. You can table it with the Clerk if you so wish.

Mrs. Christine Elliott: Sure. Okay, that's fine. If you can provide that, that would be great.

Can you just tell us the nature of your conversation with the pharmacist to and through the conversations with Marchese?

Ms. Judy Turner: I called the pharmacist and asked her to come to sit in on the call with Marchese and we

went through the reconstitution practice at Marchese with a staff member from Marchese. The DRCC pharmacist sat and listened to the conversation.

Mrs. Christine Elliott: Did the DRCC pharmacist have any direct conversation with the Marchese pharmacist?

Ms. Judy Turner: No.

Mrs. Christine Elliott: Did he or she express concern to you about the product, based on the conversation that you had with the Marchese pharmacist?

Ms. Judy Turner: Not at that point.

Mrs. Christine Elliott: And they made the decision to administer the product to the patient, notwithstanding the concern with respect to the concentration of the solution. Do you know why they made that decision or on what information they based that decision?

Ms. Judy Turner: I don't know. I wasn't part of that conversation. That was a conversation that took place with the DRCC pharmacist and the assistants in the prep room.

Mrs. Christine Elliott: Okay. So you had nothing to do with that whatsoever. I think that's it. Thank you very much.

Ms. Judy Turner: Thank you.

The Chair (Mr. Ernie Hardeman): You have one very short question left.

M^{me} France Gélinas: You took part in the meeting with Dr. Thiessen. Who do you remember being there and how long do you remember the meeting lasting?

Ms. Judy Turner: The people present were Karyn Perry; Kate, the lawyer; Dr. Thiessen; Craig Woudsma; Tamara.

The Chair (Mr. Ernie Hardeman): Is that it?

Ms. Judy Turner: Yes.

M^{me} France Gélinas: And for how long?

The Chair (Mr. Ernie Hardeman): Okay. That's the end of the questions. Your time is up. Ms. Jaczek?

Ms. Helena Jaczek: How long do I have?

The Chair (Mr. Ernie Hardeman): Seven minutes.

Ms. Helena Jaczek: Oh. Perhaps you could explain to us a little bit about what quality assurance programs you have in place within the oncology chemotherapy part of the pharmacy at Peterborough.

Ms. Judy Turner: Certainly. We have a rigorous QA and it involves checks at different parts of the process. The first would be that the physician enters the orders. The pharmacist does the check. It comes to us. The assistant gets the order or the electronic copy and the labels, and does their first check. Then they would take the the bags, whatever specific bags they require, put the labels on, get the drugs and compare the drugs to the labels. Then they would pass it in to the biological safety cabinet, where the second assistant is going to prepare. The second assistant will look at the electronic copy of the doctor's order and compare the label. There will be a volume on that electronic copy. They draw up the volume for whatever drug they are preparing. Then there's the third check, a verbal check. Then it's put into the bag.

Ms. Helena Jaczek: So essentially, two pharmacy assistants are basically checking each other's work.

Do you have any visits from Durham Regional Cancer Centre to come and check the pharmacy?

Ms. Judy Turner: We're certified once a year. I was certified through Durham, and then I trained and certified the assistants.

Ms. Helena Jaczek: Do they come physically and visit you? Is that part of the certification process?

Ms. Judy Turner: No.

Ms. Helena Jaczek: What does the certification process look like?

Ms. Judy Turner: When you first become part of our team, you spend four to six weeks on the job learning about the chemotherapy agents and the biological safety cabinet. Then, after four to six weeks, they do a written test, and they also do a manipulation test based on questions in our safe handling manual. They must achieve a certain percentage to continue on.

Ms. Helena Jaczek: We heard from the College of Pharmacists yesterday that there is a different process in different provinces related to the college of pharmacy oversight in hospital pharmacies. Were you aware of that?

Ms. Judy Turner: No, I was not.

Ms. Helena Jaczek: Prior, perhaps?

Ms. Judy Turner: No.

Ms. Helena Jaczek: So the College of Pharmacists in Ontario is doing a consultation, I guess, pretty much across the country and with Health Canada as to whether this would be advisable to incorporate that. Do you have any opinion on the matter of College of Pharmacists oversight within a hospital pharmacy?

Ms. Judy Turner: It might be beneficial at some point.

Ms. Helena Jaczek: You'd say it couldn't hurt, I guess.

Is there anything else you'd like to tell us? Something that hasn't come up in the last hour and 20 minutes that you feel you want to say?

Ms. Judy Turner: I don't think so.

Ms. Helena Jaczek: Thank you.

Ms. Judy Turner: Thank you.

The Chair (Mr. Ernie Hardeman): The official opposition, further questions?

Mr. Jeff Yurek: She can go home.

The Chair (Mr. Ernie Hardeman): You're done?

Mr. Jeff Yurek: We're tired.

The Chair (Mr. Ernie Hardeman): Well, if everybody is done—

Mr. Jeff Yurek: Chair? I'd just like to request legislative research to find stability data on compounded cyclophosphamide and gemcitabine. That will answer the refrigeration question for the committee. It's all about stability. If you can look up the stability data.

The Chair (Mr. Ernie Hardeman): Okay. Very good.

Ms. Helena Jaczek: And Chair, could we somehow, from Peterborough regional hospital, find out a little bit more about this electronic preparation worksheet, who produces that?

The Chair (Mr. Ernie Hardeman): Okay. We'll leave that with the Clerk to see what he can find out.

We thank you very much for being here this afternoon, making your presentation and helping us get deeper down into figuring out what happened. Thank you very much for being here.

With that, there being no further business of the committee, the committee stands adjourned till Monday.

The committee adjourned at 1719.

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Monday 13 May 2013

Journal des débats (Hansard)

Lundi 13 mai 2013

Standing Committee on Social Policy

Oversight of pharmaceutical
companies

Comité permanent de la politique sociale

La surveillance, le contrôle et la
réglementation des entreprises
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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 13 May 2013

Lundi 13 mai 2013

*The committee met at 1440 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIES

The Chair (Mr. Ernie Hardeman): I'll call the Standing Committee on Social Policy to order. We're meeting for a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

Just one announcement: Obviously, because of the length of the routine proceedings today, we will be short of time for the three delegations. So rather than have one delegation be cut tremendously short, we will, with the committee's indulgence, have the same length of presentations from each members and then we'll have the parties—each caucus will have 15 minutes rather than 20 to ask questions. That way, we'll treat everybody fairly and we will get the most we can out of all the delegates that are here.

ERIE ST. CLAIR LOCAL HEALTH
INTEGRATION NETWORK

The Chair (Mr. Ernie Hardeman): With that, we thank you very much. Before we start, the committee does work on sworn testimony, so we will ask the Clerk to swear in the delegates.

The Clerk of the Committee (Mr. William Short): Mr. Switzer, you wanted to be affirmed, correct?

Mr. Gary Switzer: Correct.

The Clerk of the Committee (Mr. William Short): If you could just raise your right hand, please. Mr. Switzer, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Gary Switzer: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for coming in today, Mr. Switzer. As you just heard, we will give you a 20-minute opportunity to make your statement, and then we will start with questions from each caucus.

Interruption.

The Clerk of the Committee (Mr. William Short): It's just a quorum call. It's okay. We can keep going.

The Chair (Mr. Ernie Hardeman): We can keep going, thankfully. Which caucus do we start with? We'll start with the opposition caucus for the questions—after the presentation. Okay?

Mrs. Christine Elliott: Okay. All right. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. The floor is yours to make your presentation.

Mr. Gary Switzer: Thank you for inviting me here today to speak about LHINs and our role within the health care system. I am Gary Switzer, the chief executive officer of the Erie St. Clair Local Health Integration Network, or LHIN, as we are commonly known. I am proud to be a charter member CEO, joining the LHINs in August 2005. Our acting chair, Dr. Michael Hoare, was invited to be here today; however, he is out of the country.

I report to a local board of directors with representatives from all three of our counties: Windsor-Essex, Chatham-Kent and Sarnia-Lambton. Being in this role for eight years, I've seen first-hand the evolution of the LHINs and the improvement in the delivery of health care in Erie St. Clair and in Ontario.

Prior to coming into the health care sector, I held senior executive roles in the telecom and broadcast industry in Canada and the Middle East. I applied for this role at the Erie St. Clair LHIN; I was not recruited or head-hunted. It was a conscious decision on my part to plan a career move into the health care sector. I consider my experience within industry to be an asset that could assist in the transformation of health care in our province. My experience in the private sector has served me well through my career transition.

In my time at the LHIN, I have worked provincially on committees such as the hospital working funds deficit committee; the MLPA, which is the ministry-LHIN performance agreement joint advisory committee; the hospice palliative care provincial steering committee; and the neurosurgery Ontario performance management working group, to name a few.

Cancer and cancer treatment is a serious issue. Cancer, in one form or another, has profoundly touched the lives of most of us in this room. My heart goes out to those patients, their family and their friends because during a difficult time they had to endure further anxiety over the uncertainty of their chemotherapy treatment.

The LHIN role: The 14 LHINs were established in 2005 to build a stronger health care system in Ontario. Each LHIN covers an identified geographic region and

works at the local level with health service providers and the community.

In my region of Erie St. Clair, we have 87 health service providers that serve a population of approximately 640,000 people and we fund over a billion dollars to local health care providers.

Across the province, the LHINs believe that local health care needs are best understood by people who live and work in our communities and who are able to engage the people who live there.

The word “local” is well placed in our name, local health integration network. LHINs are responsible for planning, integrating and funding local health services, and ensuring the accountability of local health service providers, including public hospitals, community care access centres, community support service organizations, mental health and addiction agencies, community health centres and long-term-care homes. Therefore, we do not have responsibility, nor accountability, for the funding of physicians, public health, ambulance services, laboratories or the provincial drug programs.

The LHINs operate within an accountability framework that is comprised of the Local Health System Integration Act, a memorandum of understanding with the Ministry of Health and Long-Term Care and the ministry-LHIN performance agreement, also known as the MLPA. This agreement outlines strategic-level targets that we must meet and relate to the improvement of the local health care system.

Erie St. Clair LHIN’s strategic directions of better care, better experiences and better value guide all of our decision-making.

Our integrated health service plan is our three-year regional planning document that provides a snapshot of our population health and clearly outlines what our priorities are in how we will measure improved care. In arriving at our priorities we engaged our communities in conversations and workshops, and spoke with front-line care providers, physicians and many stakeholders to make sure we were on the right track, with the confidence that our local health care system is in agreement on where we need to focus our resources. We can work with our partners to accelerate system transformation.

Our LHIN’s priorities are improved outcomes in alternative level of care; improved outcomes in the emergency department; improved outcomes in chronic disease management; improved outcomes in mental health and addictions; and certainly continuing to focus on better care for seniors and helping our older adults to age at home, surrounded by their life’s memories and where they are most comfortable.

We have accountability agreements with all of our health service providers that outline their specific accountabilities and performance metrics. These agreements are publicly available.

Simply put, LHINs are able to translate the provincial strategies by localizing them, so you can see a straight line from the Premier right through to the patient. Our accountability agreements with all of our health service

providers ensure there is alignment and performance measures.

Each health service provider organization is responsible for overseeing their own operations and service delivery and is governed by their own board of directors.

We therefore maintain a strategic and overseeing role in health care transformation and administration. I am proud of the work the Erie St. Clair LHIN has done in improving local health care. We build positive relationships with our health service providers, and it is because of our local connection to these agencies and hospitals that I can stand before you today and share my knowledge of, and intersection with, the chemotherapy issue. It is because we work closely with our hospitals that our internal issues management protocol worked.

We are able to share and receive information such as the situation we are all here today to discuss. In regard to the chemotherapy issue we are discussing today, as stated, we have a system-level accountability. Therefore, we did not have a clinical role, but rather, assisted our hospitals in coordinating a response.

LHINs work at the system level. We have confidence in our funded agencies to provide the direct clinical services and management of their day-to-day operations. In this particular case, we did not have a role in the procurement, distribution, administration or monitoring of chemotherapy pharmaceuticals. The clinical expertise and decision-making in regard to life-altering cancer treatment rests properly with our hospitals and health care providers.

As I’ll elaborate later in my address, you’ll see that the hospital led their response to their staff and patients, and on behalf of our LHIN, I coordinated a provincial discussion.

Timeline: With that in mind, I’ll brief you on my knowledge of, and involvement in, the chemotherapy issue. The following is my recollection on how events unfolded.

On Saturday, March 30 of this year, I first became aware of a challenge with certain chemotherapy medications through our issues management protocol with Windsor Regional Hospital. The issues management protocol is a process that we have with all of our health service providers that encourages open communication and the sharing of sentinel events with the LHIN for information, support and/or possible action.

The same day, on March 30, I was informed by telephone from Windsor Regional Hospital CEO David Musyj that they had learned of an under-dosing issue with chemotherapy medications through London Health Sciences Centre that affected an estimated 289 local Erie St. Clair patients. After he explained the issue and his action plan, he asked for my help. I realized that he needed his organization to focus on their plan to reach out to patients and mobilize their response, and that I could assist in coordinating a provincial discussion.

Mr. Musyj also provided me with Windsor Regional Hospital’s plan for informing their staff and patients. He outlined the steps they were going to undertake, includ-

ing a copy of the draft letter they were hand-delivering to patients; information on the hotline and information walk-in centre they were establishing; information on the process for the phone calls they were going to make; and a plan to engage the media through a coordinated approach.

Mr. Musyj asked for the Erie St. Clair LHIN's support on this issue, and I certainly agreed to assist where we could. I also offered to take on a provincial coordination role with other LHINs and Cancer Care Ontario. By doing this, I was able to help reduce the pressure on the hospital and move action along by coordinating the information sharing and provincial conversation. This meant that the hospital was able to apply their clinical and operational expertise and begin their patient and staff outreach.

LHINs have the ability to act both locally and provincially, and play a coordinating role to help connect all the parties.

Immediately after my discussion with Mr. Musyj, I contacted the CEO of the South West LHIN to inquire as to their involvement and plan. I asked for their assistance to coordinate activities as Windsor Regional Hospital was preparing to reach out to their patients on April 2.

As part of our issues management process, I reached out to our Erie St. Clair LHIN senior staff who was on call that weekend for after-hours issues and emergencies. I provided information to him and explained the hospital plan in place to communicate to patients and staff. In my coordination role, I also spoke with Claudia den Boer, Windsor Regional Hospital's and Hôtel-Dieu Grace Hospital's regional vice-president, cancer services, to inquire further about the involvement of Cancer Care Ontario and London Health Sciences Centre. I also wanted to further my understanding of the situation and update her on the actions I was taking.

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In speaking with Mr. Musyj and Ms. den Boer, it was apparent to me the provincial implications of this issue, and I requested a conference call for April 1. There would be representation from the three affected hospitals, three LHIN CEOs and Cancer Care Ontario.

On April 1, the conference call was facilitated by Cancer Care Ontario's president and CEO, Michael Sherar. Information was shared on the coordinated efforts to inform patients and the broader community. During that conversation, we were all made aware of the strategies each of the organizations were already taking, or were planning to take, to address the issue with their staff and patients.

Discussion around timing of the announcement for patients and the public sharing of the situation and information on where patients and their families could go to for answers—we were focused on alignment to ensure that each organization would be prepared to support their patients.

Later in the day on April 1, I spoke with our director of communications and public affairs and updated her on the situation. Our director of communications and public

affairs also informed me that our office had received concerns from members of the public regarding this issue.

Our communications staff shared Windsor Regional Hospital's messaging on our website and directed concerned community members to the Windsor Regional Hospital hotline and website for more information, as well as to Cancer Care Ontario.

During this time, Windsor Regional Hospital was holding town hall meetings for their affected patients and families, as well as their staff. Since those initial meetings, I kept in regular contact with Windsor Regional Hospital and Cancer Care Ontario.

At this time, I want to acknowledge the outstanding work done by Windsor Regional Hospital and their staff: Christine Donaldson, regional pharmacy director, Hôtel-Dieu Grace Hospital, Leamington District Memorial Hospital and Windsor Regional Hospital; Claudia den Boer, regional vice-president, cancer services, Windsor Regional Hospital and Hôtel-Dieu Grace Hospital; Dr. Gary Ing, chief of staff at Windsor Regional Hospital; Dr. Ken Schneider, chief of oncology at Windsor Regional Hospital; and David Musyj, president and CEO at Windsor Regional Hospital.

Windsor Regional Hospital responded quickly, informatively and compassionately to the patients affected within Erie St. Clair. When I initially spoke with Mr. Musyj on March 30, 2013, he shared with me his plan for responding to the issue and he had all hands on deck during the weekend to work on this issue. I was confident in his strategy and ability to reach out to his hospital staff, patients and their families, to do whatever he and his team could do to help ease anxiety and provide a compassionate response to a very difficult situation.

I read Mr. Musyj's opening statement when he appeared in front of this committee on April 22. He referenced the "just culture" at Windsor Regional Hospital. As Mr. Musyj explained, a just culture is about mutual trust. I've experienced this as an administrator and as a patient at Windsor Regional Hospital. When you work with the staff at Windsor Regional Hospital and walk the hallways, as I do, you sense the culture of mutual trust, and know that "outstanding care, no exceptions" is much more than a tag line.

In closing, for the patients and their families, I wish that this never happened, but it has.

I'm a cancer survivor myself, and when you're first diagnosed and after the initial shock, you put your entire trust into your physician, the hospital and the system they work within. It is the most vulnerable I have ever felt. However, I had faith in my physician and the system, which I still do.

I can only imagine the impact that the patients who were affected by this issue must have felt. I do know that each organization felt the same way and put in measures to address all patient concerns.

Now we need to find real answers. Now is the time to understand what system changes need to take place to help restore confidence in our excellent health care

system and reassure all cancer patients that they are receiving the care they are expecting. This is not the time to point fingers, assign blame and create divisions amongst partners. No, now is the time for the health care system, our politicians and our leaders to come together and find solutions to ensure that this can never happen again.

Thank you. I'd be pleased to take your questions.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. With that, we'll start with the official opposition. Ms. Elliott.

Mrs. Christine Elliott: Thank you very much, Mr. Switzer, for joining us today. We agree that we're all trying to find out what happened here to make sure that it doesn't happen again, and so I have a few questions for you just regarding some of the agreements that were entered into.

You mentioned on page 3 of your presentation that you have an accountability agreement with all of your health care providers, and I'm assuming you would have had one with the hospitals that were affected here?

Mr. Gary Switzer: That's correct.

Mrs. Christine Elliott: Do you recall what year those agreements were entered into?

Mr. Gary Switzer: They're entered into annually, and they're signed annually.

Mrs. Christine Elliott: Would you be able to provide us with a copy of the—have you signed one for 2013, as well as 2012?

Mr. Gary Switzer: Yes. They're on our website—

Mrs. Christine Elliott: Are they? Okay.

Mr. Gary Switzer: —and they're on each agency's website as well, but I'd be prepared to provide them as well.

Mrs. Christine Elliott: All right. If you could, that would be great. Thank you.

You also mention, on page 4, I believe, of your statement, that you didn't have anything to do with the procurement of drugs and so on. Would responsibility for that have been outlined in the accountability agreement that you had with the health care providers?

Mr. Gary Switzer: No. We don't outline what their responsibility is with respect to procurement. It's covered that they have to followed broader public service procurement rules, but beyond that with specifics, no.

Mrs. Christine Elliott: So you didn't have any specific requirements with respect to procurement of any drugs?

Mr. Gary Switzer: None.

Mrs. Christine Elliott: Okay. Were you aware that some of the hospitals were outsourcing the admixtures of chemotherapy products?

Mr. Gary Switzer: I was aware that various hospitals produced some of the pharmaceutical treatments in-house and some of it is outsourced to a third party. It's their decision based on quality, process and effectiveness. I wasn't aware specifically of any specific treatments.

Mrs. Christine Elliott: So you left that up to the individual hospitals to negotiate in their best judgment

about how to manage their resources and what was best for the patients?

Mr. Gary Switzer: Exactly. That's where the expertise is.

Mrs. Christine Elliott: Okay. Are you familiar with Medbuy as an organization?

Mr. Gary Switzer: Yes, I am.

Mrs. Christine Elliott: And were you aware that Medbuy was involved in this particular situation?

Mr. Gary Switzer: I found that out after the fact. As more information became available, I was aware of Medbuy with this specific purchase, yes.

Mrs. Christine Elliott: The hospitals wouldn't have been required to provide you with copies of any of those agreements, would they?

Mr. Gary Switzer: No.

Mrs. Christine Elliott: Before this happened, were you familiar with the contents of any of those agreements?

Mr. Gary Switzer: The contents? No, I've never seen one of their agreements.

Mrs. Christine Elliott: All right. Thank you.

Mr. Gary Switzer: Thank you.

Mrs. Christine Elliott: My colleague may have some questions.

The Chair (Mr. Ernie Hardeman): Mrs. McKenna?

Mrs. Jane McKenna: Hi. Were you aware that there was a grey area with what was going on with the brokering between Medbuy and Marchese?

Mr. Gary Switzer: Not at all.

Mrs. Jane McKenna: No? So there was never any mention at any time that there was any issues at all with Health Canada and the Ontario pharmaceutical—with the overlap, with neither of them regulating the—

Mr. Gary Switzer: The first time I heard about Marchese as a pharmaceutical supplier was when this occurred. I'd never heard of them before.

Mrs. Jane McKenna: So you were familiar with Baxter, then?

Mr. Gary Switzer: Oh, Baxter I'm aware of. I'm aware of that brand, yes.

Mrs. Jane McKenna: Okay. That's fine for me right now.

The Chair (Mr. Ernie Hardeman): With that, we'll go to the third party. Ms. Gélinas?

M^{me} France Gélinas: Good afternoon, and thank you for coming to Queen's Park. I have a few questions that I want to ask, but first, I want to clarify a few things that you said during your presentation. You sit on quite a few of the provincial LHIN committees. Do you know if the LHINs have ever looked at subcontracting of health care services?

Mr. Gary Switzer: Subcontracting—that's a broad statement. To my knowledge, no. With respect to pharmacy?

M^{me} France Gélinas: No, with respect to outsourcing in general.

Mr. Gary Switzer: Not at the committee level, but's it been discussed at the CEO level.

M^{me} France Gélinas: In what context?

Mr. Gary Switzer: With respect to the CCAC when they contract services. With respect to—a number of our organizations come together to pool their resources for shared services, for example. And then, internally—the 14 LHINs—we subcontract out our IT support.

M^{me} France Gélinas: Very good. You give out the list of agencies that are under the purview of the LHINs; I think they're the same in all 14 LHINs. In the accountability agreement you have with those agencies, do you ask for accreditations for all of them?

Mr. Gary Switzer: We don't ask for it. I know a number of them proceed to be accredited.

M^{me} France Gélinas: So could you give me an example of who could not be accredited in the list of agencies that—

Mr. Gary Switzer: Well, when I'm thinking of our agencies that we fund, the majority, to my knowledge, have been accredited. Some of the smaller community agencies—it might be a Meals on Wheels, or a small transportation provider—to my knowledge, have not pursued that path. But I know, for example, our community health centres; our CMHAs; our CCAC, of course; our hospitals, of course; our long-term-care homes—more likely, it's the smaller agencies that haven't.

M^{me} France Gélinas: Okay. And what is the value added of—if you already have an accountability agreement with them, what is the value added of doing this accreditation?

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Mr. Gary Switzer: It demonstrates that they're adhering to industry best practice with respect to safety and patient care and a number of other indicators.

M^{me} France Gélinas: Okay. And is this something that is mentioned? Once they reach accreditation, do they have to maintain it as part of their accountability agreement with you?

Mr. Gary Switzer: It's not part of the accountability agreement, to my knowledge. The agencies that have achieved accreditation, they usually go on a three- to four-year cycle to repeat it.

M^{me} France Gélinas: The strategic direction for your LHIN is better care, better experiences and better value. What do you mean by better value?

Mr. Gary Switzer: When we talk to residents in Erie St. Clair, they all want to make sure that we're good custodians of the public purse. They want to make sure that there's value for every dollar that we invest, so we ensure that we use—we look through the lens of quality to ensure that every investment is for quality care, and it's efficient and it's effective.

M^{me} France Gélinas: Would you say we have value in the services that you presently fund?

Mr. Gary Switzer: Yes, I would.

M^{me} France Gélinas: So when you set out for better value, you set out for—

Mr. Gary Switzer: Improving. We're in a race that never ends. Health care is a \$48-billion business or in-

dustry in Ontario, and there's always room to constantly improve the service that we deliver.

M^{me} France Gélinas: Okay. I'm on page 3. I don't think we have the same pages because I saw you flip not at the same time I did, but you say, "Simply put, LHINs are able to translate the provincial strategies by localizing them; so you can see a straight line right from the Premier right through to the patient." I'm quoting from what you just read.

What happens when the provincial strategies are not what—because you also say you believe that the LHINs are there to listen to the people they serve. So what happens when you have a disconnect, where the people you serve do not agree with the provincial strategy?

Mr. Gary Switzer: You know, we engage the public in a number of areas in a number of different locations, and a lot of this is education to identify what we're working on and to try to address their local issues as much as possible and how the provincial strategies are there to improve access and quality of care.

In some instances, the community wants something specifically that's outside the strategic plan for the province, and so we meet with them to try to understand what their needs are and try to reach at least an understanding, that we both understand each other's issues and the differences that we may have.

M^{me} France Gélinas: So when it comes to making a decision between the community wanting something that is outside of the provincial strategies, you're there to listen to your community, but you're basically there to translate the provincial strategies and localize them—which one wins, which one loses?

Mr. Gary Switzer: It's an interesting question. I'd say that everybody wins with respect to having local representation, managing the health care planning locally. I'd say that everybody wins. We may not be 100% all the time, but having been in these community events locally, just being there to discuss their issues with them I think is a far better position to be in than we were in previous years when they had nobody to talk to.

M^{me} France Gélinas: Okay. But at the end of the day, you maintain that your job is there to bring the strategies and implement them at the local level?

Mr. Gary Switzer: Yes, and through our integrated health service plan, which is our three-year plan for our community, we develop services around that as well. So with our region—you know, we're pretty unhealthy. We have the obese capital of Ontario in our region. We have higher diabetes, higher arthritis. We need plans locally to address those issues, and they do tie into the provincial strategies, for example, to reduce chronic disease across the province.

M^{me} France Gélinas: I thought we were the—I'm not going to fight you for it. You can keep the title. I'm more than happy—

Mr. Gary Switzer: Every LHIN wants to say, "We're the oldest and the sickest," but I'm proud to say that—well, not proud to say, but we are the most obese.

M^{me} France Gélinas: Oh, no. Nothing good; sorry about that.

All right. Does the LHIN have anything to do at all with protecting patient safety? You say better care, better experience, better value. Where do safety and quality fit in?

Mr. Gary Switzer: Each hospital has a quality improvement plan, and they have key indicators and they're all referenced back to the attributes of quality. We work with Health Quality Ontario on that as well, so we receive a copy of their annual plan.

The senior executives—a portion of their compensation is applied to achieving those quality indicators. For example, hospital infection rates would be an indicator which impacts safety. Hospital falls resulting in a fracture impact safety. Hand hygiene is another safety indicator. That's how we get at it through the QIPs, the quality improvement plans.

M^{me} France Gélinas: Now that we've seen what has happened with chemotherapy, where 1,000 people got a diluted dosage—that happens to be a drug that had been outsourced through Medbuy. When Cancer Care Ontario was here, they made it clear that every time there is a handoff, there is a possibility of error. It doesn't matter how good the health care system is; we are human, no matter the job we do. By having outsourcing, by having Medbuys, we've just added four hand-offs right off the bat. We've increased risk just by the mere fact that Medbuy exists and outsourcing exists and all of this. How do you reconcile this with your goal of better care?

Mr. Gary Switzer: I read some of the previous transcripts. Christine Donaldson, the director of pharmacy—I know Christine quite well. The process that they go through in-house to produce this chemotherapy treatment—based on their own analysis, they didn't have enough of an internal quality control to do this, and that's why it was outsourced, to certain standards of care, for the mixing of this drug.

You go to where the expertise is. In their review of the situation through Medbuy and their RFP for services, it was quite clear that they had instructions and they were based on best practices.

M^{me} France Gélinas: Not enough quality in-house, but they are doing it in-house now. Are you telling us that we don't have quality, now that they've started doing it in-house?

Mr. Gary Switzer: No. At the time that decision was made to outsource it, they felt at the time that they didn't have sufficient quality checks to do that one specific drug mix. As I understand it, they mix anywhere from 1,500 to 2,000 prescriptions daily in that hospital, so it's quite a busy spot. Now that they've brought it in-house, they've put extra due diligence on the process to double- and triple-check every step along the way. I agree with you: Transactions are where issues occur.

M^{me} France Gélinas: So why couldn't they have done this before, if it became quite easy and fast? I mean, the day that the thing was shelved, they started doing it

in-house, and they all assured us that they are doing it in a quality way.

Mr. Gary Switzer: I'd have to defer that to the hospital to answer.

M^{me} France Gélinas: Okay. You've agreed that every time there's a hand-off, there's a risk. Is this something under your "better care" lens? Is this something that you're interested in looking at: How much outsourcing is being done, how much hand-off, how much increased risk is happening?

Mr. Gary Switzer: When we look at the system level with our system partners—let's call it our 87 providers—we want to make sure that they're following best practice, that they're following procurement guidelines and that they adhere to the quality programs that they put in place.

Many of their organizations have become lean experts. It's an engineering process to take waste out of the system but also to catch the quality issues. We have ongoing discussions with them on that area, and we look at their patient satisfaction and patient experience feedback as well.

M^{me} France Gélinas: You said that you had looked at outsourcing and contracting out at the level of the CEO. Do you intend to have those discussions now with your hospitals?

Mr. Gary Switzer: As part of our agendas with our hospitals, we talk about outsourcing or third party shared services through an organization that we've set up with the five hospitals. They have an organization called Transform, and that manages procurement, logistics, IT, IM and IS. That's the type of outsource; they outsource to this third party organization that they already own. Those are the conversations we have.

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M^{me} France Gélinas: And is this something you encourage?

Mr. Gary Switzer: Yes.

M^{me} France Gélinas: I'll let it go.

The Chair (Mr. Ernie Hardeman): Okay. Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair.

Thank you, Mr. Switzer, for coming in today. You've talked a fair bit about accountability agreements with service providers in the geographic area of the Erie St. Clair LHIN. You also have a relationship with Cancer Care Ontario. How does that work? Is there an accountability agreement, or how do the two of you relate?

Mr. Gary Switzer: Cancer Care Ontario has an agreement with the regional cancer centres; they have a direct relationship there. We do not have an agreement with Cancer Care Ontario.

Ms. Helena Jaczek: In the situation that you faced, you've outlined very clearly, really, how you got the phone call, and you acknowledged that the LHIN didn't have the clinical expertise, perhaps, to get involved in the issue itself—the clinical issue—but you offered to provide a provincial coordination role. Is this something that is an expectation of the CEO of LHINs?

Mr. Gary Switzer: It's the expectation of the LHIN, and me being the CEO, yes, it is.

Ms. Helena Jaczek: That you would reach out and you would try and—

Mr. Gary Switzer: By all means. When David Musy called me that morning, he had all hands on deck with his staff preparing for the patients. I said, "I'll take on the responsibility to work with Cancer Care Ontario, putting more of a provincial view on this and organizing that."

Ms. Helena Jaczek: Through this specific incident, there was an immediate response to handle the issue appropriately. Did you find that people were being collaborative in terms of Cancer Care Ontario, other LHIN CEOs, the hospitals?

Mr. Gary Switzer: Yes.

Ms. Helena Jaczek: We've heard from you that you were one of the original CEOs when LHINs were established in 2005. Have you had challenges somewhat similar to this, where your position as CEO of your LHIN has had to cross jurisdictional boundaries perhaps to have some coordination of response? Have there been other challenges?

Mr. Gary Switzer: I've worked very closely with the South West LHIN, for example—my neighbour—with respect to patient concerns. Residents of both of those counties will cross over for care, and sometimes it's not as smooth as possible. So we work together to ensure that it's seamless for the patients.

Ms. Helena Jaczek: What about across the province? Any other issues or challenges that you've faced in your role as CEO of your LHIN?

Mr. Gary Switzer: The 14 LHINs work very closely together. We meet on a weekly basis on the telephone and monthly in person. When there are provincial issues, to launch new programs, for example—with the drug shortage issue that was recently, within the last six or seven months, we—

Ms. Helena Jaczek: The Sandoz?

Mr. Gary Switzer: Sandoz. We've identified one of our CEOs to sit on that committee for the province and feed that information back to us.

Ms. Helena Jaczek: In your role as CEO of the LHIN, do you feel confident in your role to manage these issues as they arise?

Mr. Gary Switzer: Yes. We're the system managers. We're responsible for the planning and the funding of the system, and it's really joint accountability and lateral accountability, as I say it, as well.

Ms. Helena Jaczek: You've talked quite a bit about the accountability agreements with your 87 health service providers, and my colleague from Nickel Belt has alluded to your role in terms of ensuring patient safety. Is this something that's done through the quality improvement plan? How exactly do you feel confident in your 87 health service providers that the proper kind of quality assurance/patient safety measures are in place?

Mr. Gary Switzer: I'll start at the micro level. We have concerns in some of our regions with respect to patient transportation and how critical it is for a patient to

be transported for dialysis, let's say. When patients would reach out to us, because they know who we are, and talk about the challenges they had, we were able to bring all the agencies together to get uniform practices and a system to pick up patients so that nobody would be missed, especially for critical transportation like that. So that's a patient safety issue.

With respect to safety issues in our accountability agreements, there are key performance indicators for specific things for each agency with respect to safety.

Ms. Helena Jaczek: It has been said that the LHIN, in a way, functions as the middleman between local service provision and the Ministry of Health. As you review quality improvement plans from your various health service providers, I presume if you have an issue you go to that health service provider and try to work out the issue—as an example, if wait time started increasing or something like that.

If those issues are not readily resolved, do you turn to the ministry? Can you just sort of explain to us what we believe is a very important role that you play? Can you sort of illustrate that for us?

Mr. Gary Switzer: It means we work directly with the agency. We identify what the patient issue or safety issue is, and we work with them so that there is a mutual understanding. We ask them for a performance improvement plan on how they're going to close the gap, and this is all done at the CEO and staff level.

If that fails and we don't get the results that we want, we'll have a board-to-board consultation, and we will go back to our board if we feel that we need to go deeper on this one and do an operational review. We have the powers, through legislation, to bring in somebody to do an operational review to determine what the current state is and the desired state, and put an improvement plan in place to reach that. We'll keep the ministry informed on these based on the progress of our discussions.

Ms. Helena Jaczek: And, therefore, there would be the potential to have that dialogue with the ministry if there was an issue that seemed to be very difficult to resolve.

Mr. Gary Switzer: Yes, if it's very difficult to resolve I have a regular interface with the ministry at my level with the ADM, and the DM, on occasion. My staff are always interacting with ministry staff through the LHIN liaison branch.

Ms. Helena Jaczek: Which ADM do you relate to, actually?

Mr. Gary Switzer: Catherine Brown.

Ms. Helena Jaczek: Health accountability?

Mr. Gary Switzer: Yes.

Ms. Helena Jaczek: Okay. We heard from Catherine. In your opinion—you're the CEO; you're trying to bring local issues forward—do you feel that the LHIN is working well? Are you satisfied with this kind of relationship, bridging between local communities and the Ministry of Health?

Mr. Gary Switzer: As I said in my opening statements, I'm from industry, so health care is new to me.

When I joined, the level of accountability that we had eight years ago compared to now—now we have signed agreements with everyone. They have specific targets that are tied to a strategic plan that the government approves. They balance their budgets.

Ms. Helena Jaczek: So you've seen progress? Would you say—

Mr. Gary Switzer: I've seen significant progress. I mean, our wait times have improved significantly; they are a specific focus. I'm used to measuring things in industry, and when I came in we didn't have any specific measurements. Now we do. We have clear accountability. Services cannot be changed in the system unless the LHIN signs off on it, so in the past we would have agencies balancing their budget by extending a wait time or cancelling a service. That does not happen anymore. They have to have it signed off by the LHIN if they want to change a service, because that will impact patient safety somewhere. Health care is like a large spider web. If it moves over here, you know that you're going to get a ripple effect somewhere else. It's a very complex system.

Ms. Helena Jaczek: Finally, in terms of administrative costs, in terms of the money that is received from the ministry and what is transferred out to your service providers, what is spent in administration at the Erie St. Clair LHIN?

Mr. Gary Switzer: We fund just over \$1 billion and our operating budget is around \$4.9 million.

Ms. Helena Jaczek: So a very small percentage.

Mr. Gary Switzer: Yes.

Ms. Helena Jaczek: Thank you.

The Chair (Mr. Ernie Hardeman): The official opposition, Ms. Elliott?

Mrs. Christine Elliott: We don't have any further questions. Thank you, Mr. Switzer.

The Chair (Mr. Ernie Hardeman): The third party, Ms. Gélinas.

M^{me} France Gélinas: You talked about your personal experience and how vulnerable you feel when you get a diagnosis of cancer; you look healthy, so I guess the treatment worked. There are a lot of people whose trust in the health care system has been shaken. What do you suggest, or is there anything that you can do in your position at the LHIN to rebuild that trust?

Mr. Gary Switzer: As I said in my statement, I have all the confidence and trust in the system that we have. Working in this industry—and I've worked with Dr. David Ng and Dr. Ken Schneider—these folks are very committed. My advice to any patient who is concerned is to listen to their care provider and to do some research on their own—but listen to their care provider. Nobody's intent is to do any harm at all—at all. Their interests are genuine, and it's all patient-centred.

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Ms. Cindy Forster: Welcome, Mr. Switzer. On page 2 of the report that you read from, in the third or fourth paragraph, you said, "LHINs are responsible for planning, integrating and funding local health services and ensuring accountability of local health service providers,

including: public hospitals...." How do you go about ensuring that accountability, particularly around the procurement piece? Because I don't see that as being excluded.

Mr. Gary Switzer: In procurement, we work with our hospitals on an annual basis. They have to sign an attestation that they're in compliance with the broader public service act with respect to procurement.

Ms. Cindy Forster: When they send those agreements in, what is the LHIN's responsibility to ensure that whoever they are procuring with is meeting standards that would protect patient safety?

Mr. Gary Switzer: The way we operate in our LHIN, we have a management team that interfaces with each agency at a working level. That elevates up to the CFO level and the CEO level. When we meet, on occasion—not every agenda—we talk about procurement issues and compliance with respect to the broader public service. Their individual boards have to sign off on that attestation. When it comes to us, we forward that in to the ministry, and we advise our board that they are in compliance.

Ms. Cindy Forster: Has there ever been a time, since you've been the CEO of the LHIN, when you've had a local community conflict with the Ministry of Health where you sided with the local community with respect to something that they thought they needed in health care in their community, and you had to go and advocate with the ministry for some changes? How did that work out?

Mr. Gary Switzer: I'm just trying to think of a potential conflict. I know we advocate on behalf of our providers all the time in their communities. Most recently, we supported the supervisor who was in the Hôtel-Dieu, because there was a structural deficit in that hospital. We'd like to say they were fighting above their weight. It was a structural deficit, and we went to the ministry and supported a base funding increase for them. That's what the community needed to provide those services in that trauma centre.

Ms. Cindy Forster: We've heard this year that there have been hundreds of patient complaints to the Ombudsman of Ontario, but he has no oversight over public hospitals or health care. What is the LHIN's role in actually dealing with those types of patient complaints, or do they even get to the LHIN level?

Mr. Gary Switzer: Patients call me, I'd say, on a weekly basis, not every day. We have a process in place where we respond to patients individually, and we ask them to please go back to the provider. The providers have their internal ombudsman or patient-advocate groups to go through.

If they still do not get satisfaction, we ask them to come back to us. We discuss every complaint that comes through that we forward on. We do have a discussion with the agency about it because, as you can appreciate, there are many sides to a story.

Ms. Cindy Forster: Thank you.

The Chair (Mr. Ernie Hardeman): That concludes the time. Thank you very much. More from the government?

Ms. Helena Jaczek: If we have some time, my colleague Mr. Flynn, would like to—

The Chair (Mr. Ernie Hardeman): Okay. Mr. Flynn?

Mr. Kevin Daniel Flynn: Thank you, Mr. Switzer, for your presentation. My riding is Oakville, so I'm in the Mississauga Halton LHIN. There's a variety of opinions about LHINs throughout the province. Some of the criticisms, I think, are sincere, and some of them, I think, are driven from a partisan perspective. But the relationship that I've had with my own specific LHIN has been extremely positive.

I look at some of the changes that have taken place, and like you, I'm someone that looks, as an individual, to quantitative measures when we're trying to change or reform the system. Where I've seen some real success in my own LHIN is in the field of ALC; emergency room wait times; bringing together all the mental health providers so that the people in my communities know where to go when that time comes, if that time comes. Most recently, there was a great initiative that was led by the local LHIN around the abuse of and the addiction to opioids.

A lot of these things seem to involve a strategy, the implementation of a strategy, that was going to work throughout the local system. So when you look at the reason that you're here today, one of the biggest successes that I've seen, or the reasons for the success of the LHIN in my own community, has been around its ability to be transparent, both with the patients and with the service providers themselves, and the accountability that they have to the community.

Based on those two strengths that I think the LHINs have, certainly in my own experience, how would you apply those two strengths to the issue that's here today?

Mr. Gary Switzer: The issue here today—we're totally transparent, as you said, and we have engaged our website with Windsor Regional's to direct patients there as a complete link, so we make sure everybody is aware of it. We work with the local community, when they do phone us about this issue, in providing them the material for it as well.

From a planning perspective—I'm just trying to recall back. What were the two points? You wanted—

Mr. Kevin Daniel Flynn: Well, there's one on transparency, and the other was on accountability.

Mr. Gary Switzer: Accountability: recognizing when the people of Erie St. Clair call us to identify our level of accountability with agreements with our agencies and the hospital's accountability or the agency's accountability—and we direct them to there. So it's totally transparent. All our meetings are open, and everything is on our website with respect to the agreements.

Mr. Kevin Daniel Flynn: And out of this, do you expect to have some learnings? Do you expect to learn something that would guide your future decisions?

Mr. Gary Switzer: We learn every day in health care. When you put the patient at the centre of every discussion and consider them in the room when you're

talking about it, you become acutely aware of how important it is to improve communication, especially in the transactions of care.

When patients call me, they usually have a complaint about the transaction, going from agency A to agency B, to doctor A to doctor B, and it's that hand-off that causes the grief. They say they get great care. We're working very hard on these transitions of care, trying to improve that, such as the launch of Health Links—you've heard of Health Links in Mississauga, and Halton as well—as one way to wraparound care with the patient.

Mr. Kevin Daniel Flynn: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation, and that concludes all the time—holding you up at the start, but we cleaned it up just in time, so thank you.

ONTARIO HOSPITAL ASSOCIATION

The Chair (Mr. Ernie Hardeman): Our next delegation or presentation is from the Ontario Hospital Association. Welcome. We are doing these committees under oath, so we'll ask the Clerk to either affirm or swear each one of you in before we start the presentation.

The Clerk of the Committee (Mr. William Short): Ms. Campbell, if you'd like to swear an oath, the Bible is in front of you. If you want to affirm, just raise your right hand, please.

Ms. Campbell, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Pat Campbell: I will.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. As with previous presenters, you will have 20 minutes to make a presentation, and then we will have questions. This time the questions will be 15 minutes from each caucus, and this time it will start with the third party. With that, the floor is yours, and thank you again for coming in.

Ms. Pat Campbell: Good afternoon, everyone. My name is Pat Campbell, and I'm the president and CEO of the Ontario Hospital Association. I'm joined here by Sudha Kutty, OHA's director of patient safety, physician and professional issues, and Amy Clark, the OHA's manager of issues management and media relations.

By way of introduction and background, the OHA is a voluntary, not-for-profit member association that represents Ontario's 149 public hospitals. Although we work with hospitals, the government and other health system partners to improve the quality of patient care provided by Ontario's health system, we do not have a formal or informal health system regulatory or standards-setting role like, say, Accreditation Canada, the College of Pharmacists or the government of Ontario.

In terms of my own background, I am a nurse and a former CEO of Women's College Hospital and of Grey

Bruce Health Services, so I have some direct insight into what it's like to deliver front-line care and to manage an academic hospital or a large, rural multi-site hospital. That said, I am not a pharmacist, and so my ability to answer certain scientific or technical questions you may have about pharmacy generally, or chemotherapy specifically, is limited. However, I will endeavor to obtain for the committee answers to any questions that I am unable to answer as soon as possible after my testimony today.

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On behalf of the OHA and Ontario's hospitals, I'd like to thank this committee for the opportunity to appear before you today. It likely comes as no surprise that we've been following these hearings closely, and we believe that important issues have been aired here. I view this as an opportunity to advance that discussion.

And on behalf of the OHA and Ontario's hospitals, I offer our deepest sympathies to the patients affected by this issue and to their families.

I also offer our apologies to the people of this province, because this issue strikes directly at the trust Ontarians have in their hospitals and health care system, the trust that is the foundation of our system: trust that the health care services we need will be there when we need them; trust that those services will be provided safely, effectively and efficiently; trust that the doctors and nurses, pharmacists and pharmacy technicians who work in hospitals, and the people and businesses outside the hospitals whose work supports them, are committed and capable of doing the job they were hired to do; and trust that when mistakes are made or issues identified, they'll be addressed quickly, transparently and in a meaningful, rational way.

These problems with the chemotherapy should never have happened, but I can assure every member of this committee and every Ontarian that the OHA and hospitals are committed to re-earning their trust by helping to determine why they happened and acting to ensure that they never happen again.

I'll note that these problems were discovered by hospital pharmacy technicians, who felt empowered and safe enough to bring their concerns about product quality forward to hospital management. This kind of thoughtful initiative is only possible when you have what is known as a "culture of safety" in hospitals, when staff understand that their first priority is identifying and addressing issues rather than blaming and shaming. Hospitals across Ontario have worked hard to build that kind of culture, and it is very much in the public interest.

I mentioned a moment ago that the OHA is not a hospital or health system regulator. However, we are often asked to assist the Ministry of Health and Long-Term Care with managing system-level issues that pertain to hospitals. Generally speaking, in these situations, we provide communications, information-gathering and policy advice and support to hospitals and the ministry.

The OHA first learned about this problem on April 2, effectively the same time that Cancer Care Ontario issued its first public notice. We circulated CCO's notice to

every hospital in Ontario and offered our support to the ministry in terms of managing the issue.

The ministry invited OHA representatives to participate in daily, multi-stakeholder calls about this issue, and the OHA has participated fully ever since.

When it became clear that a knowledge gap existed about which companies provide chemotherapy to hospitals, and about hospital pharmacy practices, the OHA surveyed its members on April 16 with a requested turnaround time of 24 hours. The survey results, which we received from 88 acute care hospitals representing 94% of acute care beds and 95% of acute care patient days, were verified and shared in full with the ministry and the public on April 22. I have brought copies of the survey results for the information and use of the committee today.

When the ministry requested that hospitals attest that the oversight and quality assurance policies and practices they have in place for the procurement, storage and administration of all compounded drugs are sufficient to ensure patient safety, the OHA held a member teleconference to explain the nature of the attestation and encourage hospitals to submit the attestations as quickly as possible. All hospitals have submitted these attestations to the ministry.

The OHA has also carefully reviewed the draft regulations proposed by the College of Pharmacists and the ministry, and formally submitted our recommendations based on discussions with hospital pharmacy leaders from across Ontario. I will comment more on them in a moment.

The OHA will continue assisting where we can to resolve this issue. We are looking forward to Dr. Thiessen's report and to helping ensure that hospitals have the tools and knowledge they need to implement his recommendations.

Any members of the public watching today or reading Hansard should also know that every hospital has taken this issue very seriously and has looked inward at their processes in order to ensure that their pharmacy processes are safe and effective.

As I stated earlier, we believe these hearings are valuable in terms of airing important issues regarding the current regulatory environment and hospital procurement practices. I'd like to speak about these issues for a few moments.

Obviously, questions about chemotherapy have shone a spotlight on a regulatory grey area when it comes to pharmacy practice. I have no issues with saying that, as a former hospital CEO, I knew that these services were not new in hospitals but had no idea that a regulatory gap existed, until it was brought to light seven weeks ago. This was not an issue that's been raised before.

The OHA believes there should be formal regulatory oversight of the companies that produce pharmacy products—all pharmacy products—for hospitals, and that this oversight should be clear, thoughtful and consistent across Canada. Let me explain what I mean by "thoughtful" and "consistent."

Even in the absence of formal regulation by Health Canada or the ministry, compounding has, to the best of our knowledge, been performed safely and effectively outside of hospitals for many years, in part because the companies that performed this work were generally very responsible, fully understood the needs of hospitals and pharmacists, and took their quality assurance practices very seriously. We believe that as legislators consider how to fill the regulatory gap, they should seriously consider how to reinforce and build on the best of those practices, and also the downstream implications of the new regulations in terms of their effects on the health system supply chain, even if this consideration takes some time. This issue is sufficiently complex and important that we do need to get it right.

First and foremost, any regulations that are created must actually achieve what they're intended to achieve. Secondly, we must minimize unintended consequences. For example, in our written submission to the ministry regarding its proposed amendment to the Public Hospitals Act, we noted that a number of Ontario hospitals are in communities that border other provinces or the United States—places like the Ottawa Hospital, bordering Quebec, and the Windsor Regional Hospital, bordering Michigan. We spoke with these hospitals and learned there have been situations where they have had to obtain drugs—authorized by Health Canada with a drug identification number and approved for sale in Canada—from hospitals in other provinces or in the United States.

Generally speaking, hospitals manage ongoing supply shortages pharmacist-to-pharmacist. Supply shortages can range from a back order on one product in one hospital, to a major shortage like we saw last year involving products made by Sandoz. Given the unpredictable nature of these types of situations, it's difficult to assess the frequency or how much advance notice hospitals will have before a shortage occurs.

Our concern is that the language in the draft regulation would limit an Ontario hospital's ability to manage ongoing supply situations at a local level. For that reason, we have recommended that the draft regulation be amended to allow for hospitals to purchase or otherwise obtain drugs from hospitals outside of Ontario.

We also strongly recommend that care be taken to ensure that the College of Pharmacists actually has the capacity, knowledge and resources necessary to do any work it is given by new regulations, and that this capacity be carefully considered when decisions about when the new regulations come into force are made.

In terms of consistent regulations and approaches, evidence from across the health care system shows us how important consistency is, whether it's consistency in hand-washing processes or consistency in open-heart surgery. Consistency of practice based on evidence is the driving principle behind the Excellent Care for All Act and almost all quality improvement initiatives. Consistency is also important from a trust perspective. Patients and their families and, frankly, regulators should be able to trust that, within reasonable variation based on

specific needs, health care services will be provided in a consistent manner, regardless of where they are in the province or the country.

This applies to medication, obviously. That's why we strongly believe that clear, national standards regarding the labelling of all medication should be considered. Ideally, a pharmacist in a hospital in PEI who picks up a 100-millilitre bag of chemotherapy should have the exact same understanding of its contents as a pharmacist in the Yukon or Ontario. Although we are waiting to review Dr. Thiessen's report, we do believe there is value in provincial and national regulators considering this kind of thing without delay.

Consistency is also important in terms of the legislative and policy frameworks hospitals and other health providers work in. For example, the draft regulation released for consultation by Ontario's College of Pharmacists includes a definition of "drug" that differs from the commonly understood one in the Drug and Pharmacies Regulation Act and also the federal Food and Drugs Act. We are concerned that applying different definitions to hospitals obtaining drugs and the persons or entities supplying them creates a potential for misinterpretation, and could lead to inconsistent practices. For these reasons, we have recommended that the definition of "drug" in the draft regulation be consistent with the definition being contemplated by the proposed regulation under the Public Hospitals Act and in existing and already well-understood legislative/regulatory language.

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Beyond these examples, it should be noted that the college, ministry and Health Canada are all working on regulations and policy changes in this area. We believe that any proposed regulatory changes should be considered within the broader existing legislative and regulatory framework and closely aligned with any other legislative and regulatory changes to minimize duplication of oversight and ensure uniform application across the sector. For that reason, we strongly urge all of the relevant legislators and regulators to work closely together and carefully consider the interplay and front-line implications of their proposed courses of action.

In discussion of hospital procurement practices here and elsewhere, a number of questions have been raised about the outsourcing of goods and services by hospitals. I'd like to focus on this for a few moments.

The fact is, almost everything used by a hospital, from medication to diagnostic equipment, from food to hand soap, is to one degree or another outsourced. These goods and services are brought to hospitals for use by health professionals, patients and their families. In some cases, hospitals contract directly with manufacturers. In other cases, depending upon the arrangement, a group of hospitals may share services to allow for greater expertise and collaboration in pursuit of the best solution.

Some of the reasons for this are obvious. Hospitals don't have the expertise or capacity to create medical equipment or, in most cases, basic medication, or to grow food for patient meals. But some of the reasons are less obvious, and it's important that they be fully understood.

This committee has heard that when it comes to the compounding of medications for chemotherapy, a number of hospitals outsource this practice. What hasn't come through clearly is why hospitals do this. Contrary to the assertions of some commentators and unions, the outsourcing of compounding by hospitals was not driven primarily or even secondarily by cost considerations in most cases. Rather, the OHA's survey of hospital pharmacy practices suggests that hospitals that outsource compounding do so primarily for reasons of occupational health and safety and adhering to accreditation standards related to medication management. This makes sense. The components of chemotherapy are toxic and require costly infrastructure in order to facilitate their safe compounding. Beyond that, evidence and leading practice holds that having a dedicated, external provider of chemotherapy or other medications can reduce the potential for variation and human error. Indeed, patient safety was cited as a reason for outsourcing by 31 out of 40 hospitals that purchase ready-to-administer intravenous medications.

All of this is to say that outsourcing is a necessity in hospitals for reasons of practicality, safety and best practice, and that legislators considering legislative or regulatory changes that would affect hospitals' procurement processes should be cognizant of this reality.

That said, there are specific procurement issues which have come to the fore because of this issue that should be addressed. Ontario's hospitals, and the group purchasing organizations many of them are members of, procure goods within a rigorous regulatory environment from a process perspective. What is less clear is who in the procurement process is responsible for assuring quality—prior to contracts being signed and on an ongoing basis thereafter—in order to ensure that what is being delivered is what has been ordered and paid for.

In our opinion, this responsibility should properly rest with the persons or organizations that make the products being purchased. It is here that procurement links directly with regulatory oversight of the provider's activities, whether they are providing medication, medical equipment or something else. Hospitals are skilled at providing patient care. Generally speaking, they lack the capacity to conduct quality assurance tests on products coming into the facility, even on a select or periodic basis. They must be able to trust that the products they have purchased are as advertised and understood. This is why we believe that uniform standards for the labelling of medications should be considered, and why provincial regulations governing the work of medication manufacturers and compounding be carefully conceived and sufficient to ensure quality.

Put bluntly, in the absence of effective point-of-manufacture quality assurance, compliance mechanisms like attestations imposed on hospital boards or executives that relate to how a product is used by hospital staff will paint, at best, an incomplete picture for regulators and patients.

I'll end this portion of my presentation in this way: Earlier, I mentioned the importance of trust in our health

care system. Hospitals are ready and willing to work with legislators and regulators to fully address the issues raised by this unfortunate issue, and re-earn the full trust of Ontarians. But our efforts to rebuild trust are also linked to the right decisions being made by legislators and regulators—fully informed decisions grounded in facts. For that reason, I urge all Ontarians to wait for Dr. Thiessen's report before speculating about causes, drawing conclusions about solutions or taking additional action in this complex area. For the sake of public trust in Ontario's hospitals and pharmacy practices, it's better for us all to be right about the root causes and the way forward than to be fast.

The Chair (Mr. Ernie Hardeman): Thank you very much. We'll start the questioning now with Ms. Gélinas.

M^{me} France Gélinas: Thank you for coming, Ms. Campbell. I will start where you left off, as in doing it right rather than doing it fast. Some of the comments that you have made about the regulation that the ministry has put forward—more specifically, when it comes to your members, the hospitals of Ontario, having to check who they are procuring drugs from as well as the attestation.

I think you said it well: that it should be done by whoever makes the products being purchased, not by the hospital. Given what we have in front of us and given that I represent an area where there are mainly small and rural hospitals, could you see it ever working out the way the regulations are being presented right now?

Ms. Pat Campbell: I do think that, at this point, we shouldn't be rushing to move to finger pointing or laying blame. We have a process in place that's about determining what went wrong and finding reasonable and appropriate steps to ensure that something like this never happens again.

M^{me} France Gélinas: What is the process for looking at what went wrong?

Ms. Pat Campbell: The review being completed by Dr. Thiessen that's under way will play a key role in understanding the facts, and we think it's important to allow Dr. Thiessen to complete his important work. That being said, when Dr. Thiessen's work is completed, it will be important to broadly disseminate the findings and the conclusions from that review, and to ensure that those changes are implemented going forward, complemented by appropriate education resources for hospitals, pharmacists and others to act on those recommendations.

M^{me} France Gélinas: I agree with what you just said. Two things: The mandate of Dr. Thiessen is not to find out what went wrong; it is to look at the supply chain—not to get your hopes too high there, because you could be disappointed. The second is that there is a draft regulation being circulated right now where the ministry makes the hospital responsible to make sure that whoever the deal is with is regulated. You've commented on it. My question is: Can you see it, the way it is now, ever working out? Think about the 52 small members that you have. How would it work for them?

Ms. Pat Campbell: They are an important constituency for us. At this point, we're welcoming the draft

regulations and we're welcoming the chance to comment on the draft regulations. We do think that it's important that people are being thoughtful about what to propose. We have commented on the recommendations to both the College of Pharmacists and the Ministry of Health, and we can certainly share with the committee what our comments are.

As you've pointed out, it is important that any proposed regulatory changes should be considered within the broader existing and proposed legislative and regulatory frameworks and should build on existing practices, incorporating common language and minimizing duplication. We want to ensure that we don't inadvertently impact the availability of medication.

M^{me} France Gélinas: That's good. What's the relationship between OHA and Medbuy?

Ms. Pat Campbell: The Ontario Hospital Association has a category of members that are called "associate members." Certainly Medbuy and the Ontario Hospital Association have an overlap in their membership, but we have no direct relationship with Medbuy. In terms of what it means to be an affiliate member of the OHA, it means they are eligible to apply for the healthcare of Ontario pension plan, they can have access to group benefit plans that we offer, and they can possibly receive reduced rates on some of our educational offerings.

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M^{me} France Gélinas: So you've never looked at the Medbuy procurement process, policies or contract? That's not something that the OHA ever looks at?

Ms. Pat Campbell: No.

M^{me} France Gélinas: Would you have concerns about the fact that points are awarded to different companies? When Medbuy reviews the different companies' bids for the procurement, they look at the size of the donations that will be made to the hospital in determining who should get the contract.

Ms. Pat Campbell: The idea of value-added offering by companies is not something that's unique in terms of the processes that Medbuy undertakes. The value-added practice employed by Medbuy, as I understand it, is compliant with the procurements directive, which gives you a sense of how pervasive or common those kinds of elements are.

In terms of what it means to be compliant with the procurement directive, it has to pass the test of being fair, open and transparent. From our perspective, it's better to ask about the value adds that a service provider might be considering as part of the RFP process than to not ask and have that conversation not be part of the formal process.

We think it's acceptable if this is transparent, and that's the only way it's acceptable under the procurement directive: if it's transparent and if you can appropriately and fairly evaluate the value add. In the case of the Medbuy RFP, the value add of the donation to their RED program was only used in the evaluation as a tiebreaker, but otherwise would not influence the scoring or decision on a successful bidder. So it was only a secondary consideration at best.

M^{me} France Gélinas: And how do you know that?

Ms. Pat Campbell: In terms of the conversations that have gone on since this activity came to light.

M^{me} France Gélinas: Okay. I'll let it go around.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Ms. Campbell, for your very clear presentation. I really appreciated it.

One of the areas that you've alluded to is the survey that you conducted on hospital usage of pre-compounded medications from an external provider. It is a fairly lengthy 16-page document. Could you just outline for us some of the highlights of what you found as a result of your survey?

Ms. Pat Campbell: Would it be acceptable for the committee for my colleague Sudha Kutty to address that question?

Ms. Helena Jaczek: I'm not quite sure whether there's a need for an oath, but that's a technical matter.

The Chair (Mr. Ernie Hardeman): Yes, I'm sorry; I was writing down my time here. But anyone who's going to testify must be sworn in.

The Clerk of the Committee (Mr. William Short): Did you want to be affirmed or swear an oath?

Ms. Sudha Kutty: I can swear.

The Clerk of the Committee (Mr. William Short): Swear? Okay, the Bible's there. It's Sudha Kutty, correct? OHA director of patient safety, physician and professional issues? Do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Sudha Kutty: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): There we go. Thank you. Back to the questions.

Ms. Helena Jaczek: If we could have some highlights.

Ms. Sudha Kutty: Sure. The survey really looked at the use of two different categories of medication. The first was ready-to-administer IV solutions, and bulk IV medication. This category around chemotherapy drugs fell into the category of bulk IV medications.

What the survey showed was that a very small number of respondents actually purchase bulk IV medications from external providers. Actually, only 10 hospitals were using that over a variety of different drug classes. Six hospitals were purchasing chemotherapy, two narcotics and two epidurals. The vast majority of these hospitals—nine hospitals—were purchasing from an organization by the name of Baxter CIVA. At the time of completing the survey, only one hospital was purchasing from Marchese, and that hospital was purchasing for epidurals, not chemotherapy drugs.

As Pat alluded to, this practice of outsourcing is being done for a variety of drivers, most of them related to occupational health and safety and patient safety, and that's

what our survey revealed. So that's really the highlight on the bulk mixture.

On the ready-to-use mixture side, more hospitals are purchasing pre-compounded IV medications in a ready-to-administer format—40 hospitals, to be specific. Primarily, the types of drugs that are being purchased are: epidurals, 27 hospitals; narcotics, 21 hospitals; and antibiotics, 18 hospitals. Again, Baxter CIVA has the lion's share of—most hospitals are purchasing from Baxter CIVA for those particular products. Again, the drivers for outsourcing this purchase of pre-compounded medications: patient safety, Accreditation Canada standards and occupational health and safety.

Ms. Helena Jaczek: Thank you very much.

Back to Ms. Campbell: The Ontario Hospital Association exists, in essence, as an association for individual hospitals to belong to, to have their voices heard, I presume, with the Ministry of Health and Long-Term Care. Also, as you've alluded to, very much in terms of communications—you've emphasized consistency, and I really appreciated that. So your role is very much to communicate to ensure some consistency across hospitals. Is that how you would describe it? Could you sort of flesh out what the Ontario Hospital Association is there to do?

Ms. Pat Campbell: Sure. The Ontario Hospital Association is a member association, but several years ago, the OHA recognized that hospitals don't exist in a vacuum. So, in fact, our vision is to work toward a high-performing health system and to do that in a way that recognizes that hospitals are part of a broader community of health service providers and, indeed, community providers that are required to support hospital care.

So in terms of how we do that, we do that through a variety of mechanisms, some of which are educationally focused in terms of providing education, both for hospital members and for the broader health care community. About 30% of the folks who use our educational programs don't come from hospitals. Then, we work with both hospitals and government around steps to improve the health care system. Some of those are around advocacy positions. One of our current advocacy positions, which we've been really pushing on, is increased investment in community-based services, recognizing that patients want to be home and they want to spend as little time in hospital as possible. But that's only possible for them to do that if, in fact, there's an enhancement in community-based services.

So we do work on behalf of hospitals, but we do see that, in order for hospitals to do an effective job, it really is a component of a high-functioning health care system.

Ms. Helena Jaczek: And one of your sort of core principles, I'm sure, relates to patient safety, to ensuring quality assurance. We've heard quite a bit over the last few weeks about the Excellent Care for All Act and quality improvement plans. I presume that you're involved again in ensuring that these sorts of principles are consistently expressed to hospitals—your membership, in other words.

Ms. Pat Campbell: Ontario's hospitals are all about accountability, transparency and responsibility, and that's kind of the root of everything we do. I think one of the key challenges is that health care is changing, and it's changing pretty dramatically. So supports to hospitals and others to respond to this changing environment is a key element of the kinds of things that we provide—and help them to process new regulatory requirements, understand what the implications are, how they could incorporate those into practice and support them in doing that through the creation of tool kits or other resources, education programming or other mechanisms that allow them to do that.

Ms. Helena Jaczek: In terms of the working group that was put together by the Ministry of Health and Long-Term Care, you're involved with that working group on a regular basis?

Ms. Pat Campbell: Yes. We've been involved in the working group on a regular basis—the terms of reference for the quality assurance and review working group.

Ms. Helena Jaczek: And are you pleased with the way that's being handled and your ability to contribute and being listened to? Are you finding that a useful exercise?

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Ms. Pat Campbell: We are finding that a useful exercise. I think it was really important that the number one priority that was recognized by everybody when this first came to light was a focus and a priority on reaching out to patients and their families, and giving time and space for the important work of contacting those folks and having those folks work directly with their care provider teams in terms of understanding the implications and the ramifications of this issue. We've since gone on from then, of course, to talk about the multiple review processes that are under way and how things like the need for information can be supported. That has certainly been a role that we've played on behalf of that group.

Ms. Helena Jaczek: You've commented extensively on the regulation introduced by the Ministry of Health and Long-Term Care and the fact that you were able to comment, and that some time should be taken, obviously, to review those comment. And also the working of Dr. Thiessen's study—you're anxiously awaiting the results, presumably, from his review as well.

Ms. Pat Campbell: Yes. We do think it's very important that—and this is kind of one of the principles of the whole patient safety movement: to not rush to what we call in the patient safety world “shame and blame,” but, in fact, to do root cause analysis to understand that we're applying the right remedy for the right purposes and not overlaying a whole lot of new process that adds an additional layer of complexity to what is already a very complex system.

Ms. Helena Jaczek: In terms of Health Canada, you haven't specifically mentioned them. Have you had ongoing dialogue with Health Canada on their appropriate role in this particular incident and in the future going forward?

Ms. Pat Campbell: Health Canada has also been part of that working group and participating in the working group. We don't get into the details on that working group; it's more about how to support the logistics of what needs to happen. But certainly there has been some discussion about Health Canada's role versus the College of Pharmacists' role going forward.

Ms. Helena Jaczek: Would one of those issues be this consistency of labelling nationally? You alluded to neighbouring provinces and other jurisdictions and so on. Would you see that as a role for Health Canada?

Ms. Pat Campbell: Well, certainly, of all of the people at the table, only Health Canada has a national role. The groups that we deal with on an ongoing basis around patient safety include Accreditation Canada and the Institute for Safe Medication Practices. They are both interested in and advocating for a national approach to this issue, recognizing that the challenges that have been uncovered in Ontario won't, in fact, be unique to Ontario. So we are supporting that approach.

Ms. Helena Jaczek: Thank you very much. We'll save the rest of our time.

The Chair (Mr. Ernie Hardeman): Thank you. We'll go to the opposition. Mr. Yurek.

Mr. Jeff Yurek: Thanks for coming out today. To start out the questioning, is the OHA in favour of the Ontario College of Pharmacists taking over inspecting and regulating hospital pharmacies in house?

Ms. Pat Campbell: We're certainly aware of the conversation that's going on around the appropriate role for the Ontario College of Pharmacists. Ontario pharmacies are already supported by a set of standards through Accreditation Canada that are applied as part of the overall accreditation of Ontario hospitals process. One of the core accreditation standards is around patient medication safety, so that's already in place. Ontario's pharmacists are all covered by the College of Pharmacists, so they already have a level of jurisdiction in Ontario's hospital pharmacies at the present time.

We do think that, going forward, we need to ensure that the public policy solution actually addresses the problem that's been identified, and that's the process we're currently in. In order for the public policy to be effective, we need to know what went wrong and what should accurately prevent it from happening. At this point in time, from our read of the situation, the problem isn't actually in hospital pharmacies; it relates to the manufacturing process or the process outside of the hospital systems.

Mr. Jeff Yurek: You've stated that "the OHA believes there should be formal regulatory oversight of the companies that produce pharmacy products—all pharmacy products—for hospitals," and I agree with that. But I think the regulatory oversight needs to have an understanding of the complete system, which would include hospital pharmacies.

We have an email between Marchese and OCP given to committee stating that OCP didn't know who Medbuy was. So how do you have OCP cover regulatory frame-

work of just 80% of the system and ensure that there's compliance within the whole system? You're leaving out the hospital pharmacies when you take a look at excluding them from the oversight of the Ontario College of Pharmacists. How do you—

Ms. Pat Campbell: Well, I think the important piece, as we get through this phase, is to ensure that we have the right oversight in the right places by the right people. In our view, at this point, what's really needed in relation to this chemotherapy issue is that hospitals need assurances that they are receiving products of the highest quality. In our view, the role of hospitals is to provide quality patient care, not to provide oversight or to be regulators of pharmaceutical supplies, and in the area—

Mr. Jeff Yurek: That's not my question, though. My question's about the College of Pharmacists overseeing hospital pharmacies.

Ms. Pat Campbell: But it is related, in that for the public policy solution to be appropriate, it needs to address the root cause of what the issue is. From our point of view, the root cause of the issue was not in-hospital pharmacies; it was in relation to the products that were received from outside of the hospital.

Mr. Jeff Yurek: That's your root cause analysis? So—

Ms. Pat Campbell: I think it's important to realize that everyone has a role to play as we move this forward, but in terms of the College of Pharmacists having overall inspection of hospital pharmacies, I think we need to be careful about overlaying multiple levels of accountability, multiple levels of review on any system, and make sure that we've got the right level of responsibility and accountability in the right places.

Hospitals are already subject to a great deal of oversight. They have boards that are in place to be accountable for the quality of the patient care that is provided within hospitals. So the question in our mind has to be: What would be the additional value that would be placed on the College of Pharmacists having jurisdiction to also inspect hospital pharmacies? That's an open question in our mind, at this point in time, as we work through the remainder of the review process.

Mr. Jeff Yurek: But you agree with the College of Pharmacists having oversight of the individual pharmacist—even though, I assume, the same things that you just said are in place in the hospital to oversee that their pharmacist is providing accurate patient care in doing their job?

Ms. Pat Campbell: Well, that's currently the system we have in place, where the regulated health professions are governed under their individual colleges. So the College of Pharmacists is very consistent with other regulated professionals within the hospital environment.

Mr. Jeff Yurek: So they could probably do the job of overseeing hospital pharmacies?

Ms. Pat Campbell: Hospital pharmacies are already overseen by hospitals and by hospital boards. So the question that we're asking is: What is the additional value added for the system in having an additional level

of oversight? It isn't a question of competence, although I think we would have to consider that as times goes forward, because that would be a new role for the College of Pharmacists.

I think the other piece, though, that all of the system—the health care system's a very complex environment, and one of the things that we do have is a lot of standards and a lot of regulation that is already in place.

In terms of drug therapy, Accreditation Canada has a series of standards that hospitals have to meet. One of four core standards is, in fact, the medication management standard. It's one of the four core things that is looked at in any accreditation survey that comes to any hospital.

I don't know if you're aware of the accreditation process, but it's very extensive. You have experts and leadership in different hospitals who come from outside the system and spend a number of days looking at the hospital's adherence to the different standards that apply to that particular facility, of which medication management is one of the four central ones. They spend a number of days providing that oversight, and that process is already in place and it supports continual advancement of the system, both through enhancements of the standards, as well as enhancement of the capacity to do the review and provide the feedback on where the hospital could continue to improve.

We actually think there's a need to examine the role that Accreditation Canada—the standards under which Accreditation Canada reviews hospitals now could potentially play a role as part of this overall review of how this incident took place.

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Mr. Jeff Yurek: You made note in your testimony here that “they must be able to trust that the products they have purchased are as advertised and understood.” It's common knowledge that Health Canada allows for IV bags, pre-made, to have overfill in them—100 millilitres, 250 millilitres, 500 millilitres, one litre etc. Wouldn't you think it would have been wise for Medbuy to be as plain as day in their contract to specify the concentration of the drug they expected to receive?

Ms. Pat Campbell: The process that we are currently involved in right now will point to where things could have been more sufficiently addressed. Certainly, hospitals have a responsibility through their procurement processes to be clear about what they're procuring and at what standard. That being said, hospitals need to be able to count on the quality of the product as specified in the contract—

Mr. Jeff Yurek: That was my question.

Ms. Pat Campbell: —and on the information provided on the packaging. When packaging says that gloves inside are latex-free, the hospital needs to be able to assume that that is the case, and so too with compounded medications like those delivered in this instance. Hospitals need to be able to assume that the concentration and the volume specified on the bag is what's in the bag.

Mr. Jeff Yurek: But they didn't ask for concentration. That was my question. Don't you think that would

have made sense, to actually put the concentration you expect to receive from the supplier on the bag you're going to be receiving?

Ms. Pat Campbell: You have information that I don't have in terms of what was specified. What we understand is that a concentration-specific request was made in terms of the procurement of those solutions.

Mr. Jeff Yurek: I have the contract. I don't know if I have it right here, but basically, it said “four grams in 100 millilitres,” which isn't a concentration. Don't you think it would have made sense to put “37 milligrams per millilitre”? That way, it doesn't matter what overfill is in the bag; they know the bag they receive would be—I'm throwing out 37 milligrams per millilitre because that was the concentration that the hospital at Lakeridge had figured out. Do you not think that if you just put, “I want cyclophosphamide at 37 milligrams per millilitre,” in 100 millilitres or 500 millilitres or whatever millilitres you wanted it to be in, you would never have to worry about overfill in the whole system?

Ms. Pat Campbell: The issue of overfill is something that pharmacists are well aware of in the system. As I understand it, four milligrams per 100 millilitres is still a concentration-specific requirement.

Mr. Jeff Yurek: It's not a concentration.

Anyway, you've also made note that procurement directive value adds were okay as per the procurement directive for breaking ties.

Ms. Pat Campbell: That's as we understand it, yes.

Mr. Jeff Yurek: Did you know that this government banned value adds in the pharmacy industry two years ago, but still allow it in the hospital? Do you think that maybe that's a double standard out there?

Ms. Pat Campbell: Well, clearly from the way you've identified it, it is a double standard. What we're responsible for is making sure that hospitals are operating in light of the procurement directive. Under the current procurement directive, it's acknowledged, and as long as it's dealt with in an open and transparent manner, it's not outside the directive.

Mr. Jeff Yurek: Do you think it made sense at the time—when they were reviewing how value adds were done in one sector of this province, that maybe they should have looked over the whole area? If it's bad in one area, do you not think it should have—I agree; I think it should have been banned across the board, across the whole province for every department. I don't really agree with value adds. Do you not think that would be—as the head of the OHA, do you think that's not a smart thing to do?

Ms. Pat Campbell: Well, I will comment on my understanding of the RED program that Medbuy runs. It does provide support to hospital staff to be able to access training. Hospitals are always challenged with being able to provide the amount of training that they need. The process for allocating the RED funds is separate from the procurement process, in that it's a totally separate competition.

So while I understand the concern about the question about value add, there is a real benefit to the hospital

community in some of these things—as long as it's done in an open and transparent manner, it's very clear what the rules of the game are and it complies with the required directives. That being said, if the rules of the game change and if their directives change, hospitals will be very open to adapting and changing their processes in that regard.

Mr. Jeff Yurek: I'll wait till the next—

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Gélinas?

M^{me} France Gélinas: Should I go ahead first? Okay.

The first thing I went to is a comment you made. It says, "There is value in provincial and national regulators considering this kind of thing without delay." I couldn't agree more. Can you think of a valid reason why it was not worked upon in 1998, when it was discovered; it was not worked upon in 2003 when there was a directive; it was not worked upon in 2008 when, here again, there was documentation between Health Canada and the Ministry of Health that there was a grey zone? But now you state that it needs to be looked at without delay. Can you think of a valid reason why now it needs to be looked at without delay, but six months ago it could have sat for another 11 years?

Ms. Pat Campbell: I think that those kinds of questions, I'm hoping, will be addressed as we go through these review processes that are under way. Certainly, from hospitals' perspective, it is our contention that all parts of the pharmaceutical chain need to be under regulatory oversight and that that should be addressed.

M^{me} France Gélinas: And you see that oversight not resting with you or your membership but resting with a level of government, either provincial or federal?

Ms. Pat Campbell: In terms of the regulation or the issue of oversight of outsourcing, certainly I don't think that hospitals should be trying to provide verification of the standards that manufacturers are to address independently. They should be able to rely on their suppliers to provide what they say that they are providing.

M^{me} France Gélinas: I agree. My next question: You say, "Contrary to the assertions of some commentators and unions, the outsourcing of compounding by hospitals was not driven primarily, or even secondarily, by cost considerations in most cases."

A couple of questions about this: Who are the unions that are saying this?

Ms. Pat Campbell: To be honest with you—apparently, it's OPSEU that has been saying this.

M^{me} France Gélinas: And in what forums did they say that?

Ms. Pat Campbell: I'm aware there's been some media reporting of that.

M^{me} France Gélinas: Okay. How about commentators?

Ms. Pat Campbell: I think it's media commentators that have made an assumption about the reasons why hospitals would go to outsource activities.

M^{me} France Gélinas: So we look at the website of Medbuy. Their entire front page—and it doesn't matter

where you click on this, it always comes up that they will save you money: "Hospitals, join us. We will save you money." Why should we believe that they're not there to save money if this is what they say on every page of their website?

Ms. Pat Campbell: Certainly one of the benefits that hospitals look to accrue through group purchasing organizations can be savings through larger group contracts. However, you have to look at the reasons why any individual business decision is made, and in terms of this particular activity, the reason to move to group purchasing was not driven by cost savings. It wasn't—

M^{me} France Gélinas: Okay. I have a hard time with your answer, because the statement you make, that it was driven by occupational health and safety—they all brought it back in. They are all doing it now with the same staff, with the same training, with the same equipment they had before. So are you telling me that all of those workers are at risk?

Ms. Pat Campbell: Certainly, these drugs are toxic, and when you're mixing and addressing large volumes of them, there are two key risks: One is toxicity and the other repetitive strain injury. I know from personal experience that the issue of patient safety is paramount in terms of trying to address these particular drugs safely and effectively. So, yes, they will all—all hospital pharmacies are capable of producing these drugs. Is that the best way? No. Accreditation Canada and the Institute for Safe Medication Practices both have standards that say that that is not the best way for these drugs to be prepared and supplied on an ongoing basis.

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The Chair (Mr. Ernie Hardeman): One minute left.

M^{me} France Gélinas: So, if we go to those documents you just referred to, we will see that they suggest that you outsource the admix medication, although you're sending it to an unregulated field?

Ms. Pat Campbell: I don't think any of the accreditation standards contemplated that the supply source was unregulated. The standard under the Accreditation Canada program—the organization purchases commercially manufactured medications, when available, to minimize compounding—is in fact the standard of care that's identified as preferential under the Accreditation Canada standards.

M^{me} France Gélinas: If you could send us a copy of this, as well as a copy of—if it's not the same—adhering to accreditation standards related to medication management. That's under your hospital procurement practice statement. If you could table that with the Clerk, please.

Ms. Pat Campbell: We'd be happy to do that.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time for the third party.

We will now go to the government side. Mr. Flynn.

Mr. Kevin Daniel Flynn: Thank you, Pat, for your presentation. I'm thinking now, when something like this happens, your thoughts turn, as a legislator, to your constituents and the variety of ways that they interact with the system. I suppose the average person's inter-

action with pharmaceuticals in general, the typical interaction: You feel sick, you go to the doctor, the doctor would prescribe a prescription, you'd take that prescription to somebody with the training of a Mr. Yurek, and you'd trust that that individual had given you the pill or the liquid or whatever it is that was going to make you feel better. There's a level of trust that runs throughout there that those professionals have served you in the way they should.

A visit to the hospital is a little different, in that you go in for a procedure—perhaps it's planned, perhaps it's unplanned—and a lot of that interaction with the pharmacist is very limited; in fact, it probably is non-existent. But you get administered a drug, you get given a drug. When I heard that, I thought, okay, I'm interested in my own hospital, so I went, and I've actually seen the attestation that came from Oakville Trafalgar Memorial Hospital, for example, because I wanted to be sure that in my own community things were being done the way they should be.

So, from a very practical level, from a patient perspective, what kind of reporting exists within the organizations that belong to you, the hospitals that are your members, that ensures that drugs are prepared properly and are administered appropriately?

Ms. Pat Campbell: There are many elements to that question, but I'll start with the two simplest. All hospitals in Ontario are accredited under Accreditation Canada. The medication safety standard is one of four core standards that all hospitals have to comply with, and any deficits in those core standards are seen very seriously as priorities for improvement.

The second I'd point to is the requirement that limits scope of practice for certain providers, limits the administration and distribution of medication to only a limited set of providers in our system. Under the scope of practice for those providers, there are specific requirements about what kind of training and expertise nurses, RPNs, in certain instances, and so on need to have to be able to deliver and administer medications, and that also applies, of course, to the pharmacists. So we rely very heavily on the fact that everybody plays a role and has a role to play and that they're trained and accountable for the role that they have within the system.

Mr. Kevin Daniel Flynn: I'm aware of a situation that exists now in Oakville. We're building a brand new hospital there in Oakville, and it's costing over \$2.5 billion, and there are all sorts of improvements and best practices that are being put into place there. One of the things that the people who are building the hospital and the staff at the old Oakville hospital are saying about the new Oakville hospital, one of the major improvements they talk about is the use of vending machines on the actual floor for the medical professions to go and get the prescriptions they need for the people on the floor.

Is this a field that's constantly under review, how you can do better? Obviously, we want to save money in the system if we possibly can, but we don't for one minute ever want to jeopardize patient health or safety. Are there

any other advances? Does this make the field more accountable, all these changes that I see taking place, that would involve, perhaps, the use of vending machines? Can patients in Ontario be confident in the safety of the drug supply in Ontario's hospitals?

Ms. Pat Campbell: I think patients can very much be confident of the drug supply in Ontario's hospitals. That being said, there are always things that we can do to improve any system, and Ontario's hospitals are open to the need to constantly improve.

I think one of challenges that we will all face is that hospital care and health care in general is changing and it's increasingly complex. Chemotherapy is a very good example of that, where increasingly the medication that's provided is individualized and identified for that patient alone.

So we will constantly be looking at our mechanisms for supporting effective delivery of patient care services, and the use of robots to support effective medication management is something that's just beginning to be looked at and used in Ontario's hospitals. It's very exciting, because it in fact increases the level of standardization that can happen and the systematization of the care delivery process in a way that supports more effective patient safety.

Mr. Kevin Daniel Flynn: Thank you. Do I have time left?

The Chair (Mr. Ernie Hardeman): Yes, you have about a minute.

Mr. Kevin Daniel Flynn: About a minute? Okay, this can be very brief—a very short answer.

Obviously, when we have an issue like this arise, there's a lot of interaction between the ministry, between the association, between the college, between patients. How would you characterize your relationship right now with the ministry on this issue?

Ms. Pat Campbell: I think we have a very mutually supportive relationship, in terms of just trying to get to the facts of what needs to be done and look at pragmatic solutions that can help move the system forward.

Mr. Kevin Daniel Flynn: Thank you, Mr. Chair.

The Chair (Mr. Ernie Hardeman): Thank you very much. We go to the opposition. Ms. Elliott.

Mrs. Christine Elliott: Good afternoon, Ms. Campbell. Thank you very much for appearing before the committee.

We've heard from your presentation that the OHA was aware that a number of hospitals were contracting out the preparation of certain admixtures for certain types of products. I'm just wondering if your association had ever issued any policy, directives or suggestions to hospitals with respect to procurement or with respect to this contracting out procedure at all.

Ms. Pat Campbell: Certainly, with the identification and initiation of the procurement directive, the OHA did a lot of member support around interpretation and understanding about what the procurement directive required of hospitals, and supported the implementation of that directive across the system.

Mrs. Christine Elliott: When would that have been done?

Ms. Pat Campbell: When the directive was first issued, but we could certainly clarify what exactly we did and when we did it and provide that back to the committee.

Mrs. Christine Elliott: If you could, and provide us with a copy of the directive, that would be great. Thank you.

The other question I have: It seems that when a number of hospitals were negotiating this whole process, they did use Medbuy as their broker or agent in the whole transaction. Could you explain to me, if you're aware, how this would happen and how that process would be initiated by the hospital, and the relationship between the hospital and Medbuy concerning what they were asking for and how that came to be reflected in an RFP, for example, such as was issued by Medbuy in the present case?

Ms. Pat Campbell: I can speak in general about how hospitals use group purchasing organizations, but in terms of the details about this specific contract and this specific engagement with Medbuy, we're really looking to Dr. Thiessen's review to highlight that. So I'm not going to speak to that.

1630

Really, hospitals use group purchasing to create efficiencies in the procurement process by performing commonly required tasks once and not having to do it hospital by hospital over and over again; also, the leveraging of purchasing power to drive costs down. But I think, more importantly, the group purchasing organizations have expertise in what is increasingly a more and more complicated procurement process, with many requirements for hospitals to navigate. GPOs not only streamline the process, they add an extra layer of confidence and reassurance that hospitals are meeting those strict accountability measures that are in place for procuring goods and services. So there's kind of a dual role that is played.

Mrs. Christine Elliott: How would that actually happen? Would there be a contract between the specific hospitals and with Medbuy, for example—

The Chair (Mr. Ernie Hardeman): Okay, that will be the last question, if you—

Mrs. Christine Elliott: —to act as their broker agent, and would that outline what their requirements were?

Ms. Pat Campbell: It can happen a number of ways. Sometimes the hospitals sign on and the procurement is done for that group of hospitals. Sometimes a few hospitals sign on to start a procurement but then other hospitals can add in and take advantage of that group purchasing. It just depends how it's constructed as a process when it's initiated.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time available.

M^{me} France Gélinas: Before these good people go home, they were scheduled to stay till 4:40. Being respectful of their time, rather than calling them back, we

still have a few questions. I was wondering if the time between now and the time that they were scheduled to stay until could be split evenly between the three caucuses?

The Chair (Mr. Ernie Hardeman): I stand to be overruled. I mean, it was agreed as to the time that we were going to use. The time isn't always necessarily—in this case it was—used equally by everyone. The time that was saved from the start was in fact very disproportional to which party it saved time from. But I stand here at the will of the committee. If you wish unanimous consent to carry on, we can carry on and divide the time that's left till 4:40 equally among the parties.

M^{me} France Gélinas: Thank you.

Interjection: Agreed.

The Chair (Mr. Ernie Hardeman): We have agreed. With that, we will start with the third party.

Ms. Cindy Forster: Thank you for being here, Ms. Campbell.

The Chair (Mr. Ernie Hardeman): We're dividing about eight minutes equally.

Ms. Cindy Forster: We've heard from a number of people who have come and made presentations over the last couple of weeks about the increased risk to patient safety with multiple more hand-offs in this procurement practice. Where meds are actually mixed in the hospital, you get a doctor's order, it goes to the pharmacy, it comes back to the nurse, and that's the end of it, right? But through this procurement process, the hand-off may be multiplied by four times. What is the OHA's position on that inherent risk to patient safety?

Ms. Pat Campbell: Again, it becomes a question of are we clear about what problem we're trying to solve and do we have the right mechanisms to solve the problem. Certainly, in terms of hand-offs, we know from patient activity that more hand-offs can create challenges. What solves that problem is effective communication and the need for effective communication processes. I go back to, in this instance, the need for effective labelling as being one of the solutions that could really help with the challenges in this particular process going forward. I think that that would go a long way to helping with the issues or the potential risks in this kind of process.

I think we need to understand that hospitals will need to procure good services on an ongoing basis. We need to have effective mechanisms to do that. There are good public policy reasons for the broader public sector accountability—

Ms. Cindy Forster: I have one more question. I just have one minute, so my next question is that we heard from Ms. Gélinas about the fact that the federal government had made the province aware, on a number of times over the last 20 or 25 years, of the lack of oversight and there was no action. Do you believe that if we had Ombudsman oversight, like every other province in this country, that perhaps the Ombudsman would have picked up on this with a review much earlier than in 2013?

Ms. Pat Campbell: Certainly, we're aware of the conversation around the role of the Ombudsman, but

actually, in this particular case, we don't believe that the Ombudsman would have played a role in terms of this. This wasn't initiated as a result of a patient complaint; this was initiated as a result of a concern raised by a hospital staff member who moved it up the chain. It immediately triggered the minister to exercise her power pursuant to the Public Hospitals Act to appoint an inspector. There was no gap in response relative to any gap in oversight.

Ms. Cindy Forster: So just the OHA—

The Chair (Mr. Ernie Hardeman): Okay, thank you. Your time is up. The government: Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Mr. Chair. You explained to my colleague Mr. Flynn that the relationship with the Ministry of Health and Long-Term Care is a positive one in terms of dialogue and so on. You sent the letter to ADM Catherine Brown of May 6 on your concerns about perhaps acting in too much haste related to the regulation, the clarification around definitions and so on. That was May 6. We're only at May 13, so I don't suppose you've received any formal response, or have you had any verbal communication in relation to your comments on the draft regulation?

Ms. Pat Campbell: As I understand it, and I look to my colleagues, the response of the public consultation on these regulations is just getting initiated and being started. So no, I don't believe we've heard any response, and neither would we expect to in that immediate term.

Ms. Helena Jaczek: But would you say that you would expect to be listened to very seriously as the representative for Ontario's hospitals? Is that the kind of experience that you've had in the past?

Ms. Pat Campbell: That has certainly been our experience: an openness to dialogue and to really understanding and unpacking the issues so that we end up in a place that actually supports improved patient care.

Ms. Helena Jaczek: Thank you for your very detailed response in the letter to Catherine Brown; I'm sure it will be looked at very closely.

The Chair (Mr. Ernie Hardeman): The official opposition: Ms. Elliott.

Mrs. Christine Elliott: Thank you. I'd like to quickly get back to the relationship between the hospitals and Medbuy since they were going to be acting as the hospitals' agent. Would you be able to advise us if, in the present case, there was a contract between the hospitals involved and Medbuy? If so, could you provide us with copies of those documents?

Ms. Pat Campbell: It is my understanding that there was a contract between Medbuy and the hospitals. We can certainly look into that; I don't know if we can provide it to you, but—

Mrs. Christine Elliott: All right. If you are able, I'd appreciate it if you could provide it. Also, was there someone who would have been designated from a hospital to work with Medbuy to make sure that the product that they wanted to have procured actually was procured?

Ms. Pat Campbell: Certainly in the initial bid process, hospitals would have been part of that initial evaluation team. Sometimes in doing a collaborative process, some hospitals participate and some don't, but they rely on their colleagues from the other hospitals to participate and be a proxy in the evaluation process. It is the hospitals' responsibility to review the product specifications and perform due diligence when the product is received and to ensure that it meets the identified clinical requirements. But this typically wouldn't include a re-evaluation of the quality of the products or the qualifications of the supplier; that would have been done as part of the procurement process.

Mrs. Christine Elliott: Okay. We certainly heard that there was a discrepancy between Medbuy and Marchese as to the product that was to be supplied. Do you suppose there could have been any discrepancy between the hospital and Medbuy in the first place as to what it was that they wanted to have procured?

Ms. Pat Campbell: I don't believe that to be the case because what was being procured was very much understood within the hospital community to be used in the way that it was used, so I don't believe that that would be the case. But communication is always something that can be addressed and improved. Looking to labelling specifications would be our recommendation as to how to improve this particular situation going forward.

Mrs. Christine Elliott: Okay. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much, and thank you very much for making your presentation this afternoon.

Ms. Pat Campbell: Thank you. Good luck.

CENTRAL EAST LOCAL HEALTH INTEGRATION NETWORK

The Chair (Mr. Ernie Hardeman): The next presentation is from the Central East Local Health Integration Network. For clarification, since we are right back on time to the original schedule, I guess I want it understood that we will then revert back to the original schedule, which would be the full time for all the committees.

Interjections.

The Chair (Mr. Ernie Hardeman): Okay. Just wanted to make sure.

Thank you very much for coming in to talk to us this afternoon. As we are doing this under oath, we'll ask the Clerk to administer the oath first.

1640

The Clerk of the Committee (Mr. William Short): Ms. Hammons, I'll start with you. Oath? Okay, great.

Ms. Hammons, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Deborah Hammons: I do.

The Clerk of the Committee (Mr. William Short): Thank you. And Mr. Gladstone?

Mr. Wayne Gladstone: Yes.

The Clerk of the Committee (Mr. William Short): Same thing. Mr. Gladstone, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Wayne Gladstone: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): With that, thank you very much for coming in. As we do with all the delegations coming in, you'll have 20 minutes to make a presentation. At the conclusion of the presentation, we will have 20 minutes of questions from each caucus. This time, I think we start with the government caucus. With that, thank you again, and the floor is yours.

Ms. Deborah Hammons: Good afternoon. My name is Deborah Hammons, and I am the CEO of the Central East Local Health Integration Network, a position I've held since 2007.

I began my career in health care as a nurse and have held senior positions in health care organizations throughout Canada, including the Vancouver General Hospital, the Ottawa General Hospital, the Toronto Hospital and the Hamilton Health Sciences Corp.

As executive director of Fairhaven, a 256-bed long-term-care home in Peterborough, I oversaw the development of a new \$25.5-million facility, led the organization in achieving their first three-year Canadian Council on Health Services Accreditation—Accreditation Canada now—and implemented an information strategic plan to create a state-of-the-art computerized environment.

I am joined by Wayne Gladstone, chair of the Central East LHIN board of directors. Wayne joined our board in June 2010, becoming board chair in June 2011. As senior vice-president of finance and administration at OMERS, the Ontario municipal employees retirement system, for 15 years, Wayne's responsibilities included corporate strategic planning, financial controls and reporting, the risk management framework, and financial and technology support.

I would like to thank the members of the Standing Committee on Social Policy for inviting us to appear before you today as you undertake a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

Wayne and I would like to begin by speaking as local residents of the Central East LHIN and acknowledge the worry and anxiety felt by patients receiving care at our hospitals when it was discovered that there had been an underdosing of chemotherapy drugs at hospitals in Ontario and New Brunswick.

As a former nurse, long-term-care home administrator and hospital administrator, I know how challenging the journey can be for patients and their family members as they undergo treatment for cancer. It is vitally important that they have trust in the system, and as LHINs we share in the responsibility of ensuring that their trust remains strong.

That is why, when this issue first came to our LHIN's attention, we immediately participated in a process of

connecting with our provincial colleagues and our local health care providers involved in the Central East regional systemic therapy treatment program to ensure that, from the patients' and family members' perspective, their concerns and their questions were addressed as quickly as possible.

Mr. Wayne Gladstone: I would like to give part of the presentation now. As part of our statement today, we would like to take a few moments to tell you about the Central East Local Health Integration Network and the role we play in managing the local health care system.

The Central East LHIN, as a geographic region, is a mixture of urban and rural geography and includes Scarborough, Durham region, Northumberland county, Peterborough city and county, the city of Kawartha Lakes and Haliburton county.

Created by the Ontario government in March 2006, the Central East LHIN is one of 14 not-for-profit agencies that works with local health providers and community members to determine the local health service priorities of our regions.

As LHINs, we work with our with local health service providers, patients, consumers, clients, caregivers, doctors, nurses, front-line staff, volunteer boards, and municipal and provincial representatives to plan, integrate and fund local health services delivered by hospitals, community care access centres, community support services, long-term-care homes, community-based mental health and addictions services and community health centres.

As you know, at the present time, while we do not have direct responsibility for the funding and accountability for doctors, public health and emergency management services, we do work closely with these groups in our day-to-day work, engaging them in our activities and seeking their input and advice. We are also not responsible for the oversight of the provincial laboratory system or the provincial drug program.

While we do not directly provide services, our mandate is to plan, integrate and fund health care services. As LHINs, we oversee nearly two thirds of the \$48.9 billion being invested in health care in Ontario in fiscal 2013-14. At the present time, over 140 health service provider organizations are funded by and accountable to our Central East LHIN for providing health care services based on signed accountability agreements. These accountability agreements reflect both provincial priorities and our local strategic directions and priorities for the health care system.

Since 2007, our LHIN has been focused on the achievement of four strategic directions: transformational leadership, quality and safety, service and system integration, and fiscal responsibility. I would like to briefly comment on each of those.

"Transformational leadership" means that the Central East LHIN board will lead the transformation of our local health care system into a culture of interdependence. We do this by demonstrating accountability and systems thinking in all decision-making and leadership actions,

rewarding innovation which is aligned with the LHIN's integrated health services plan, and modelling fair, transparent and honest interaction with one another and with our health service providers.

In turn, we expect our health service providers to bring forth integration opportunities aligned with our integrated health services plan, self-organize to solve problems, and proactively manage their organizations beyond organizational boundaries.

"Quality and safety" means that the LHIN board will ensure that health care will be person-centred in safe environments of quality care. We do this by considering quality and safety as a filter for LHIN decision-making, ensuring that no LHIN actions or decisions will impact negatively on the quality or safety of the health system. We measure and monitor the public's confidence in the health system, and we have established a health professional advisory committee with an added mandate for safety and quality.

Again, in turn, we expect our health service providers to be accountable for demonstrating improved quality and safety of clients and their caregivers, to achieve standards and targets for safety and quality of services in their service accountability agreements, and to demonstrate that patient satisfaction indicators are routinely collected and monitored.

Talking a bit about "service and system integration," it means that the board will create an integrated system of care that is easily accessed, sustainable and achieves good outcomes. To achieve this direction, the LHIN board ensures that the community is engaged to identify opportunities to enhance their health care experience. With input from our communities, we also create and implement strategic plans, such as the integrated health services plan, or IHSP, that will serve as a guide for local decisions on health care.

We expect health service providers to align their service and strategic plans with the goals and objectives identified in the integrated health services plan, participate in LHIN planning activities, support implementation, and self-identify opportunities that advance the performance of the local health system.

Finally, "fiscal responsibility" means that resource investments in the Central East LHIN will be fiscally responsible and prudent.

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As a board, we maintain a primary focus on quality as a driver for cost-effectiveness; measure cost-efficiency against our strategic priorities; evaluate investments against return on investment and the long-term sustainability of the public health system; make investments in community-based programs that prevent or shorten hospital admissions; and ensure that the LHIN is appropriately resourced. For our health service providers, this means they are to maintain a primary focus on quality as a driver for cost-effectiveness, measure cost-efficiency against strategic priorities, and make budgetary and programmatic decisions with a clear understanding of the impacts on other health service providers.

Ms. Deborah Hammons: I'm going to go ahead.

As a LHIN, we recently released our third integrated health service plan. This document sets out a shared goal for the local health care system to help Central East LHIN residents spend more time in their homes and in their communities. The integrated health service plan provides the road map for Central East LHIN hospitals, long-term-care homes, community health centres, community mental health and addictions agencies, the community care access centre and community support services to follow as they work together to create an integrated community-based health care system that can respond to changing demographics, financial challenges, updated evidence-based clinical practice and new technology.

As the LHIN works with the system towards the achievement of our strategic directions and integrated health service plan goal, we are very aware that each health service provider organization is governed by its own board of directors and is responsible for overseeing its own operations and service delivery to ensure that they meet the performance and service obligations outlined in their signed accountability agreements and the various legislation overseeing their operations.

Copies of each of the health service providers' current accountability agreement are posted on the Central East LHIN website, along with a breakdown of the funding they receive from the LHIN and a report on the system's quarterly performance. In all cases, it is the responsibility of the LHIN to ensure that the organization is aware of and complies with our expectations as defined in the accountability agreement.

The actual day-to-day operational processes that a health service provider organization puts in place to run its organization are the role of that organization. The accountability agreement only remains in place if the LHIN is satisfied that the actions of the health service provider will achieve the contracted outcomes.

Since our creation in 2006, we have exercised the word "integration" in our name numerous times to support and endorse a number of partnerships, transfers, mergers and amalgamations between health service providers that have led to better health, better care and better value for money. Examples include the merger of the Canadian Mental Health Association in Lindsay with the Canadian Mental Health Association in Peterborough. This was the result of a facilitated integration process supported by the LHIN. The new CMHA Haliburton, Kawartha, Pine Ridge now consists of 138 full-time employees who support the delivery of community-based mental health services across the four counties. With a combined operating budget of \$11.1 million, over \$230,000 in back office savings have been realized and are being redirected into front-line care.

To ensure the sustainability and the continued provision of vital palliative and end-of-life services to local residents, the LHIN supported two facilitated integration processes, the first between two hospice service providers in Northumberland county and Community Care

Northumberland, and the second between Hospice Kawartha Lakes and Community Care City of Kawartha Lakes. Front-line staff from the three hospice organizations were retained, the strong leadership base for this type of specialized service stayed in place, and the integrations occurred without any disruption in service to hospice and palliative patients.

Working with hospitals, we have streamlined access to vascular and thoracic surgery, cardiac rehabilitation, and supported the expansion of Rouge Valley Health System's Code STEMI program to Lakeridge Health in Oshawa and the Scarborough Hospital.

We also built a unified stroke system across the Central East LHIN. We obtained the funding to have Lakeridge Health Oshawa designated as a district stroke centre, partnering them with the stroke centre already in place at Peterborough Regional Health Centre. This allowed Lakeridge to hire specialized clinical staff and begin administering clot-busting drugs, commonly called TPAs, that minimize the effects of a stroke.

Most recently, we worked with 10 community-based agencies in our Durham cluster to develop an integration plan that aims to provide or improve client access to high-quality services, create readiness for future health system transformation and make the best use of the public's investment.

We are just starting a process in our Scarborough cluster that involves two hospital corporations working in partnership with our physicians, front-line staff and local communities. Their deliverable is to design and implement a Scarborough cluster hospital services delivery model, again to improve client access to high-quality services, create a readiness for future health system transformation and make the best use of the public investment.

Wayne and I are both very proud of the work being done by the LHIN staff and, indeed, the staff, leadership and boards of all of our Central East LHIN health service providers to improve the health of our communities through innovation and collaboration while recognizing the need to sustain and enhance the delivery of vital health care services in a challenging fiscal environment.

Two of our Central East LHIN hospitals have appeared before you already—Lakeridge Health on April 23 and Peterborough Regional Health Centre on April 30 and May 7. As Lakeridge Health's CEO stated during his presentation, every one of us is involved in health care in order to improve the lives of our patients. The same holds true for the team at the Central East LHIN.

As a LHIN, we first became aware of the underdosing issue through an email sent to us by Cancer Care Ontario on Saturday, March 30, that referred to an issue related to chemotherapy drug underdosing with the regional cancer programs in London, Lakeridge and Windsor. As our colleagues from Lakeridge told you when they were here on April 23, this led to a table being established by Cancer Care Ontario, the affected hospitals and the LHINs to share information and coordinate efforts to inform patients and the broader community.

The LHIN participated in two telephone conversations on Monday, April 1.

The first conversation, led by Cancer Care Ontario, included the three LHIN CEOs—myself, Gary Switzer from the Erie St. Clair LHIN and Michael Barrett from the South West LHIN—along with representatives from Lakeridge Health, Windsor Regional and London Health Sciences Centre.

The conversation was focused on developing a co-ordinated outreach plan to effectively communicate with affected patients and their families. During that conversation, we were made aware of the formal processes that each of the organizations were already taking or were planning to take to reach as many people as possible, including couriered letters and phone calls, setting up face-to-face meetings between affected patients and hospital staff and affected patients and their physicians, the opening of a dedicated 1-800 number to answer questions and concerns, and posters in treatment areas.

The group also talked about engaging with the media to ensure that people were aware and knew who to contact for more information, and shortly thereafter news releases and updates were sent out to patients and the media and posted on the hospitals' websites.

Based on our previous experiences in managing health system issues, we asked if other providers beyond those on the call had been notified.

The team from Lakeridge Health confirmed that they were reaching out to other systemic therapy providers in our LHIN, which include the Scarborough Hospital, Rouge Valley Health System, Northumberland Hills Hospital, and, as you are aware, Peterborough Regional Health Centre, which had one affected patient as well.

The second conversation that the LHIN was involved in on April 1 was called by Lakeridge and included the LHIN, Lakeridge Health leadership and their colleagues at Peterborough Regional Health Centre, and again focused on effectively communicating with patients and their families.

In the days that followed, staff at the Central East LHIN have continued to monitor the efforts of our hospitals—Lakeridge Health, Peterborough Regional and others—in responding to their patients, supporting their physicians, nurses and pharmacy staff, and ensuring that everyone has access to the most up-to-date information on the impact of this situation.

I am extremely proud of the steps that the hospitals in the Central East LHIN took to identify the issue, alert their provincial and local colleagues, partner in the development of a coordinated outreach strategy, and take the very necessary and personal steps to contact patients and their families as quickly as possible.

Mr. Wayne Gladstone: In conclusion, I would like to state again that we have a very strong system of health care providers in the Central East LHIN region who are working together to improve access to quality care for local residents.

By working with our providers, the LHIN is ensuring that local decisions are being made to respond to local

health care needs. Health service providers are being held accountable for the taxpayer dollars they are given, and with the support and direction of the LHIN, the health care needs of the people in our communities are being identified, coordinated and addressed as a truly integrated system.

Thank you very much for allowing us to make this statement. We would be pleased to answer any questions you may have.

1700

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. We'll begin with the government caucus. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Ms. Hammons and Mr. Gladstone. That's what I would call a very comprehensive report. As you were going through, I was ticking off a lot of the questions that I had for you.

To get back to this particular incident and issue, as we know, the discovery in Peterborough was on March 20 by those splendid pharmacist technicians—or assistants, as they are now, soon to be technicians, no doubt. Is it surprising to you in any way that you first heard about the incident on March 30? In other words, that was 10 days later.

Ms. Deborah Hammons: I think what the hospitals—or I know what the hospitals did. They wanted to do their due diligence before notifying the LHIN. In the case of Peterborough, obviously, it was only the one patient. But when it came to Lakeridge and the other hospitals, there were many more that were involved. In the case of Lakeridge, they wanted to go through all of the files to make sure that they had an accurate count and could come to us and tell us exactly the extent of the problem. I appreciated the fact that they were alerting us to what they had done so that we could make sure that we understood and we could discuss what we would do on a go-forward basis.

Ms. Helena Jaczek: And of course they had contacted Cancer Care Ontario—

Ms. Deborah Hammons: Yes.

Ms. Helena Jaczek: —through the Durham region cancer service, essentially.

Ms. Deborah Hammons: They have. Their relationship to Cancer Care Ontario is unique. They have their funding agreement and accountability directly with CCO. They're funded directly by CCO, and their performance agreement is directly with them, so it's not a surprise to me that they would have reached out and made that call first to CCO.

Ms. Helena Jaczek: And as we heard—as you just described and as we heard from Mr. Switzer from the Erie St. Clair LHIN, there's no direct relationship between the LHIN and CCO; it's between the hospitals and CCO.

Ms. Deborah Hammons: That is correct.

Ms. Helena Jaczek: So when you started getting involved, you saw your role—how would you describe your role as CEO of the Central East LHIN?

Ms. Deborah Hammons: In these cases, it's more of a coordinating and facilitating role. Oftentimes, when we are involved in these cases, we will make sure that the communication is effective, that it has been broad, as I mentioned in my statement. We also always have connectivity with the ministry so that they are fully briefed on what the issue is, and we already knew that that had taken place. It was more of a coordinating and facilitating role in this particular instance.

Ms. Helena Jaczek: And you've given us many examples of what has occurred within the Central East LHIN over the last few years. Ms. Hammons, you've got a long history in health care, as you've detailed to us. Maybe you're not the most objective person to ask, but do you think the LHIN's role is a valuable one? Can you, through your experience through the years, encapsulate for us what you see as the critical role of the LHIN?

Ms. Deborah Hammons: I've been at the—not the very first CEO at our LHIN but the second. I've been in the position for six years. It is phenomenal to me, the changes that I've seen, the fact that all of our health service providers have accountability agreements and that we are keeping them accountable with performance measurements that they have to report to us on a quarterly basis.

Before the LHINs were in place, there were many instances where hospitals were not balancing their budget. I'm proud to say that I think across the province we've had an excellent record. All of the health service providers in our LHIN, of which there are over 140, are all balanced. That was not the case when we first came into our role. Many facilities were not balanced. That's a significant change.

The other change is integration of the system. We've heard as we've been out talking to the public that transitioning our system is difficult, that it's very difficult for them to understand the role of different health service providers, so we've spent a lot of time looking at how we can better integrate the health care system. How can we clarify that for the public? We've spent a lot of time doing it, and we've been quite successful.

Ms. Helena Jaczek: One of the issues that has come up in conversations we've had as colleagues on the government side is that sometimes there appears to be a lack of consistency across the various LHINs. Services are provided in ways possibly to meet local needs, but sometimes it's rather hard to discern. Can you describe how LHINs communicate with each other and what role the ministry plays to ensure some degree of consistency and sharing best practices, the forums that you use for that?

Ms. Deborah Hammons: Three questions in one.

First of all, there shouldn't be an assumption that across the province everything was equal at the beginning when LHINs were first formed, because it wasn't. There are differences across the province. We've got the north, where we have a lot of rural hospitals and agencies. In the south, we've got an urban setting. It's very different. As far as providing consistency, we are there as

local health integration networks, so we're really trying to focus on the local issues that we find, and they're very different. For instance, in the Central East LHIN, because we have that rural and urban, what is needed in, say, the Scarborough area, is very different in the north. So we have to take into consideration the local needs.

As far as providing consistency, the LHIN CEOs actually meet either by telephone or by OTN or face to face at least weekly. We have these conversations on an ongoing basis as we're dealing with issues or we're dealing with the plans that the ministry is rolling out—their direction to us and how we will implement it. Those kinds of discussions go on on a regular basis.

We also relate to the LHIN liaison branch. That is an organization that we're in constant contact with. I can list many, many reasons why we make contact with them.

We also have meetings once a month with the ministry. This is with all the ADMs, the deputy minister and all 14 LHINs. That's how we communicate what's happening in the province, and also, we can report back to the ministry about what we're doing so that they can keep in constant contact with us.

As well, as you've heard, Catherine Brown is our ADM. She meets with the LHINs on a regular basis, on a one-on-one basis at our meetings, or we also have quarterly meetings with her when we're talking to her about our performance. We do have an accountability agreement with the ministry. They're monitoring to ensure that we're meeting our performance obligations with the ministry.

There's a lot of dialogue going on day-to-day—many ways that we keep in contact.

Ms. Helena Jaczek: We heard a little bit about a shortage of supply, the Sandoz situation, earlier. Were you involved? Did you have a role—

Ms. Deborah Hammons: I happened to be the provincial lead with the Sandoz shortage, so I worked very closely with the ministry on that. There was a special branch that helped support that process with us. We had a small working group.

Our LHIN was actually very instrumental in developing some of the protocols that were used provincially. We made sure that there was a web of call-outs so that we were ensuring that all of the LHINs were kept apprised.

As well, in our LHIN particularly, we had close contact with all of our pharmacy directors. That was very instrumental, because we were able to quickly know where there were issues. We actually moved drugs from one LHIN to another if there were shortages. That's the kind of thing that we would do in an issue management type of situation.

Ms. Helena Jaczek: So you feel that the structure as it exists at the moment is working well—the LHINs structure?

Ms. Deborah Hammons: That would be my opinion, yes.

Ms. Helena Jaczek: We've heard about the accountability agreements with individual hospitals. Again, you're going to have some people performing really,

really well, and perhaps not performing as well in other areas. Describe for us, if you would, how that works out. Supposing you have someone whose wait times or an organization whose wait times are increasing. How do you handle that?

Ms. Deborah Hammons: In the accountability agreement, it's outlined that if they're not meeting their performance, the LHIN can issue a performance factor. We have done that where we have had instances—we give them a couple of months, and of course through dialogue, but if there isn't an improvement, we will actually write to them and suggest that they come up with a plan of improvement to improve that specific performance factor. They usually come back to us—if we've issued a performance factor, that's something that we expect: The CEO would come and present to our board with a plan. That has happened where they have come in and talked about what the issue was, what their plan is for improvement, and we would monitor that.

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If there still isn't satisfaction in moving forward for whatever reason, we do have the capability to bring in somebody to do an operational review. We have had instances in certain hospitals where we've asked for an external review to come in, and they have presented a report. The hospital or whatever organization would work on the directions that the external review would expect, and the LHIN would monitor that.

Ms. Helena Jaczek: Then, as a recourse, in case of ongoing difficulties, as you said, you can rely on the ministry—you have that dialogue—to step in if required.

Ms. Deborah Hammons: That's true.

Ms. Helena Jaczek: And then how do you engage the public in the Central East LHIN? How do you engage stakeholders, the public? How do you make yourselves accountable to the population?

Ms. Deborah Hammons: Well, we've used various techniques. Certainly through our integrated health services plan, we've used face-to-face groups, focus groups. We actually did an Ipsos Reid study where we did—through a random sample across our LHIN—telephone surveys. We've also used the Internet where we've had the capability of the public to respond to certain issues.

Certainly, whenever we've done our integrations, it's important for the public to be engaged in that, so there's a process of communication either electronically allowing them to provide input into what we're doing. Whatever we do, that's a requirement: that we must engage the community. Of course, we have to set out opportunities to do that, and the timing of that varies.

Ms. Helena Jaczek: To Mr. Gladstone, do you feel confident, as chair of the board, and your board of directors, that everything that Ms. Hammons is doing is to ensure transparency and accountability to the population you serve?

Mr. Wayne Gladstone: Absolutely. We find at the board level that there is an openness conveyed by the staff to share information at a good level. They're

working very hard to make sure that they are delivering on their responsibilities. The board is very satisfied.

Ms. Helena Jaczek: Just one last question, at least from me. This was something I posed to Mr. Switzer. In terms of administrative costs, of the amount of revenue that you receive from the Ministry of Health that you transfer out, what percentage is used for administrative costs?

Ms. Deborah Hammons: Our budget is about \$2.2 billion, and our administrative overhead for our LHIN is just over \$5 million.

Ms. Helena Jaczek: So a very small percentage.

Ms. Deborah Hammons: A very small percentage.

Ms. Helena Jaczek: I think we'll reserve any time we have left, Mr. Chair.

The Chair (Mr. Ernie Hardeman): To the opposition. Ms. Elliott.

Mrs. Christine Elliott: Good afternoon, Ms. Hammons and Mr. Gladstone. It's good to see you again, and thank you very much for appearing before the committee.

I have some questions just based on your submission. On page 5, you talk about quality and safety and having a health professional advisory committee with an added mandate for safety and quality. I'm just wondering if you could explain a little bit about what the committee does and what kinds of inquiries it undertakes.

Ms. Deborah Hammons: This is a committee that was set out in our legislation. It's an expectation as part of the LHSIA that there be a health professional advisory committee set up. On that committee, there are six physicians and representation from a lot of the regulated health professionals, but there are some that are actually specified in the act. So physicians, nurses, pharmacists, dietitians and physiotherapists are on that committee. We meet on a quarterly basis. We look at a number of issues. They actually reviewed the quality improvement plans that the hospitals were expected to implement so that they were aware.

They're an advisory committee to the boards. We ask them for their input. They look at things like the human resource impact within our LHIN, how we are doing as far as ensuring that our patients are connected to a family physician, so that we have statistics that we can show in relationship to that.

We also make them aware of what's happening in the LHIN, keeping them apprised of the activities. So when we developed our integrated health services plan and we were going out for community engagement, they were one of the committees that we asked for their input on the directions that we're going: Is it the right way from their perspective? So we've asked for their input. So anything that we do, we keep them apprised and ask their advice on it.

Mrs. Christine Elliott: Would the hospitals be required to report to the committee a departure from their normal procedure? For example, contracting out the preparation of admixtures? Would anything that specific come before them?

Ms. Deborah Hammons: Well, one of the members—actually, the co-chair is a pharmacist, and so depending on who sits at the table, they actually bring to the table interest from their perspective. We didn't have a meeting. Our meeting was held before, so it may have come up at our meeting, but I can tell you that when we had the Sandoz issue, I actually heard about the problems because she was working in one of our pharmacy departments. I heard about the shortages before that, before the Sandoz issues became so critical. I actually had conversations with the ministry about this because this was an ongoing concern. So they alerted me of the fact, and then very shortly after that, the Sandoz issue became quite difficult, actually, in the province. So there are some fairly granular issues and questions that come up at the table, but it varies depending on the individual.

Mrs. Christine Elliott: Do you know if this particular issue ever did come before the committee? I ask that question because Lakeridge had only recently adopted that procedure.

Ms. Deborah Hammons: There were no issues about this that came forward, no.

Mrs. Christine Elliott: But would you have expected anything like this to have come forward to the committee?

Ms. Deborah Hammons: If, after the—it'll be interesting at our next meeting what comes up. There may be some questions that would be asked of us. It's hard to say. I don't know. It may have come up.

Mrs. Christine Elliott: Were you aware as a LHIN that this procedure had been adopted by Lakeridge?

Ms. Deborah Hammons: No, I was not. We were not aware, no.

Mrs. Christine Elliott: Would you have expected to have been made aware of it overall?

Ms. Deborah Hammons: Well, this is quite an operational issue, and it's the expectation that this type of operational issue would be managed through the various committee structures and the board.

Mrs. Christine Elliott: Thank you. I'll just hold on to any further questions for the moment.

The Chair (Mr. Ernie Hardeman): And the third party: Ms. Forster.

Ms. Cindy Forster: Thank you. Good afternoon. I just want to go back to the quality and safety issue and kind of the accountability of the LHIN board. Your presentation said that "the LHIN board will ensure that health care will be person-centred in safe environments of quality care." How do you actually accomplish that through your LHIN? How do you monitor it? How do you evaluate it?

Mr. Wayne Gladstone: Thank you very much. The LHIN board relies on the accountability agreements, and part of the accountability agreements include performance standards and metrics that we have for hospitals. We have 14 major metrics that we use, and they report to us on a regular basis on them. I'll just give you some examples: the 90th percentile wait time for cancer surgery; the 90th percentile wait time for cataract sur-

gery; the 90th percentile wait time for hip replacement—I can go through all of them, but we have those kinds of measures in place so that we can see whether the hospitals are meeting those requirements or not. If they're not, then we go into the process which Ms. Hammons described, wherein if there's a significant deviation, particularly, they'll be asked to remedy it. We have had that experience at the board level, where we've had hospitals coming in under performance improvement plans to remedy a specific measurement that was off track.

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Ms. Cindy Forster: And do you do any periodic audits to ensure that the information you are receiving is actually accurate?

Ms. Deborah Hammons: Yes, we do audits. I can say that most of the audits we've done have been more financially related. As you know, there is an attestation that the hospitals do on a regular basis. We receive the information quarterly from them—not directly from them, but through different agencies. I have not had a concern about the information that the hospitals share—that it was inaccurate.

Ms. Cindy Forster: We've heard from the Auditor General and we've heard from certainly the public that there have been hundreds of patient complaints in the last fiscal year. How does your LHIN actually deal with patient complaints, or do they even get to your level?

Ms. Deborah Hammons: We do get patient complaints; fortunately, not many. But we do have a very robust issues management process that we use. Any complaint that comes to us is immediately responded to, and then there is follow-up on any of the complaints.

If it is an issue that's related to one of our organizations, in fairness to them, we write to them and ask them to respond to the issue and copy the LHIN so that we know they've responded. Obviously, if the public is not satisfied with the response, we'll hear back from them.

Ms. Cindy Forster: You said that you actually meet with your counterparts in the other LHINs across the province in a variety of ways throughout the year. Has there ever been any discussion about Ombudsman oversight of health care in this province, as happens across the rest of this country?

Ms. Deborah Hammons: There has not been any discussion.

Ms. Cindy Forster: And would your LHIN actually support Ombudsman oversight of health care?

Ms. Deborah Hammons: On occasion, we've had a few calls from the Ombudsman on issues where they do not have jurisdiction. What they have done in the past is, if there is an issue that's in relationship to an organization they do not have jurisdiction over, we'll have a discussion about the problem and I will approach the organization and get back to the Ombudsman. That has been a very successful way of managing whatever issue the Ombudsman has, to have that dialogue with the Ombudsman's office—not the Ombudsman particularly, but with the office—and then rectify the issue. It has been very successful.

Ms. Cindy Forster: So based on that, you wouldn't be opposed to Ombudsman oversight of health care in this province?

Ms. Deborah Hammons: I think that the system right now seems to be working okay. Any concerns that have been brought to my attention through the Ombudsman or any complaints that we've had from the patients or relatives that are dealt with in our LHIN—we have had good success. We track everything that we've addressed, so it seems to be working.

Ms. Cindy Forster: The Ombudsman's office thinks they need oversight of the health care system in this province. I just wanted to get your views. Thank you.

M^{me} France Gélinas: Actually, I'll use this as an example: I have that thick of petitions from people—about that thick of it comes from your LHINs—who want Ombudsman oversight. How are you going to handle something like this, where the people in the geographical area that you serve want something—they want Ombudsman oversight—but the ministry does not? You are there to implement the policies of the ministry but you're also there to listen to the people who live in the geographical area of your LHIN. How do you handle that?

Ms. Deborah Hammons: I have never had anybody come to me saying that they want Ombudsman oversight. What they come to me about is what their concern is, and what we have done in every instance where we have received a concern is to address it, either directly, if we can, or through the health service provider.

If there are MPPs in our LHIN who have issues, we encourage them to bring those issues forward to us and let us know. We have a very robust relationship on those kinds of issues and try to resolve them with the MPP offices.

M^{me} France Gélinas: What kind of investigative power have you got when you go into a problem like this with an agency? Are you allowed to do investigations of practices of the different transfer payment agencies that you supervise, like the Ombudsman would do?

Ms. Deborah Hammons: That is a very broad question. Could you be a bit more specific?

M^{me} France Gélinas: Sure. Do you have a team that knows how to do investigations of complaints of third parties?

Ms. Deborah Hammons: It depends on what the complaint is. I said that we do have and have done audits, for instance, on financial matters, and we do have people on our staff that have the designation to do that, so—

M^{me} France Gélinas: How about when it has to do with care?

Ms. Deborah Hammons: There is a process—I mean, the hospitals or the agencies, if there are issues of care, if they have come to our attention, we have dealt with them, as I have mentioned.

M^{me} France Gélinas: But do you have investigative powers of care issues within the hospital?

Ms. Deborah Hammons: If there was a complaint, normally we would turn it back to the hospital to respond to that complaint, and they would investigate the com-

plaint at the hospital level and respond back to us. We look at the response that they've given us. I can't recall an incident where the patient who has complained, or the family member, hasn't been satisfied, or at least they haven't informed us.

M^{me} France Gélinas: I will share about 30,000 of them with you just so that you have—

Ms. Deborah Hammons: All from the Central East LHIN?

M^{me} France Gélinas: No. About that thick are from the Central East LHIN. I'll share them with you—

Ms. Deborah Hammons: I would like to see those, actually.

M^{me} France Gélinas: —but basically, there are people who have gone through the internal process of the hospital. They have not found closure, they are not happy with the outcome of the care they have received, and they turn towards the Ombudsman to complain and the Ombudsman answers, "I cannot. I don't have jurisdiction over the hospital." But I'll leave it at that.

That was one example of the community wanting something. I want to know: How do you handle the community's wish for something versus government policies for something? Because when people complain about the LHINs, including yours, they complain about, "You are there to implement the wish of the ministry; you are not there to listen to us." If you have not heard that before, then I would be quite surprised, because we hear it all the time. First, have you ever heard anybody say, "Your LHIN is there to implement ministry policy; it's not there to listen to us"?

Ms. Deborah Hammons: I don't recall that.

M^{me} France Gélinas: I have heard it. How would you answer me?

Ms. Deborah Hammons: Well, I would want to talk to the individual who talked to you and understand more about what the issue is that they're concerned about. You know, not knowing what they're speaking about in broad terms, it would be difficult for me to respond.

M^{me} France Gélinas: So you cannot foresee a situation where the wish of the population won't be the same as the wish of the ministry?

Ms. Deborah Hammons: Well, the ministry does a lot of engagement on their own to come up with what their directions are across the province, and I think that the directions that they are giving are quite in line to what we're hearing locally.

M^{me} France Gélinas: I want to come back to the procurement. Right now, the LHINs don't do anything with the local hospital in terms of their procurement policy?

Ms. Deborah Hammons: We don't. That's really a governance issue at the local board level.

M^{me} France Gélinas: Okay. But you do admit that there is a part of procurement policy that has to do with protecting patient safety. We've just seen that drugs being procured had a little bit of a patient safety issue, as in 1,000 people did not get what they were supposed to.

Ms. Deborah Hammons: There is a directive that the hospitals are expected to follow as far as procurement is concerned.

M^{me} France Gélinas: That deals with the money side of the procurement. How about the safety side?
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Ms. Deborah Hammons: Well, I don't have the procurement directive memorized, but I'd be surprised if it didn't say something in there about safety and quality.

M^{me} France Gélinas: So you trust that what was in there about safety and quality is sufficient and worked?

Ms. Deborah Hammons: Obviously in this case it didn't, because it actually revealed that there was a grey area that was not covered by regulation.

M^{me} France Gélinas: Whose job is it to put those regulations in place?

Ms. Deborah Hammons: Dr. Thiessen is doing his study. I think he's going to look at the supply chain process and give some recommendations to who should be regulating it, whether it's Health Canada, whether it's the College of Pharmacists or if it's a regulatory change that the government puts in place. It could be any number of those.

M^{me} France Gélinas: Could you see yourself as having a role?

Ms. Deborah Hammons: We're not an expert in pharmaceuticals. The procedures in pharmaceuticals—I think that should be left up to people who are experts.

M^{me} France Gélinas: You both talked about the trust issue. What are you doing right now to help rebuild the trust within the geographical area you serve?

Ms. Deborah Hammons: I think the most important part in this is to ensure that communication is robust and getting out—I think it will be absolutely essential that, once there is the report from Dr. Thiessen and perhaps the results from this group, we need to make sure that the public is aware of what we're doing about this issue that has just come up. We need to make sure that the grey area is resolved. So I think communicating is the most important thing. We have been in discussions with Lake-ridge and Peterborough—in their case, it was fairly simple—to make sure that the people were communicated with and that there is ongoing communication within the hospital to support the families and the patients who were involved in this.

M^{me} France Gélinas: I'm assuming that yourself and everybody else involved in the health care system has done a little bit of soul-searching right now as to what has happened. Can you see any role that your LHIN could play in preventing a situation like this from happening in the future?

Ms. Deborah Hammons: There are regulations that the organizations are to follow. They could be specifically incorporated into our accountability agreements, perhaps, and there is the attestation which is expected. In this case, the hospitals weren't aware that there was a grey area. So it wasn't done maliciously or on purpose.

M^{me} France Gélinas: They didn't know.

Ms. Deborah Hammons: They didn't know.

M^{me} France Gélinas: We've talked a lot about every time there's a handoff, there's an increased risk in the health care system. It's well known. Do you agree?

Ms. Deborah Hammons: Yes.

M^{me} France Gélinas: The RNAO has put forward a position that says that the handling of the home care contract should be done directly by the LHINs rather than by the CCAC. What do you think of that idea?

Ms. Deborah Hammons: I can speak for myself, not for all the other LHINs.

M^{me} France Gélinas: You're the one I'm questioning, so go ahead.

Ms. Deborah Hammons: I just want to be clear that this is my opinion on this. I don't want to become a direct service provider, and I think this would take us into the realm of getting too close to that. I think the role that we're playing as far as system leaders and trying to ensure that the system is working well, that the transitions are being dealt with appropriately, is a good role for us. I do know that in other provinces where they have, say, for instance, eliminated boards, their regional authorities get very involved in the day-to-day operations.

Certainly, if my opinion was asked—and you've asked my opinion—I'm quite happy with the relationship that we have with our CCAC. It's working very effectively. They have very good expertise in the management of contracts. As a matter of fact, when we go out—the LHIN itself, we actually rely on them to help support us in the absolute development of RFSs if we do, and they work with us very closely. So they're quite expert in doing that.

M^{me} France Gélinas: If we look at that expertise, why do you figure hospitals go through Medbuy and other group purchasing agencies rather than simply: take all of your hospitals within your LHIN, have their purchasing departments work together and develop the expertise in-house to do the subcontracting out? Why is a third party involved?

Ms. Deborah Hammons: Well, not all of the hospitals are equal. Some are smaller and would not have the expertise. They rely heavily on group purchasing agencies like HealthPRO and Medbuy to help support them. They have built up the expertise on how to properly contract out, so it's a way of extending their resources, if you will, by working with a supply chain organization.

M^{me} France Gélinas: It can be viewed that the supply chain organization, the group purchasing organization, is very good at doing procurement, but maybe not so much at ensuring patient safety and ensuring care. Don't you figure the LHIN has a role to play in this?

Ms. Deborah Hammons: When they're developing the RFPs or RFSs, the people who are sitting around the table developing the contracts are people who are experts in the area. In the case, for instance, of this incident that we're talking about, there were pharmacists who were developing the contracts. There were pharmacists who were actually rating the responses to the RFSs—

M^{me} France Gélinas: How do you know that?

Ms. Deborah Hammons: Because that's the process that Medbuy uses.

M^{me} France Gélinas: And the pharmacists would be pharmacists from the hospitals?

Ms. Deborah Hammons: They're pharmacists, so they're a regulated profession.

M^{me} France Gélinas: I realize, but—

Ms. Deborah Hammons: I don't know which pharmacist, who they were. Maybe I shouldn't make the assumption that they were pharmacists from the hospitals. It could be pharmacists from hospitals, it could be a pharmacist working in a number of organizations.

M^{me} France Gélinas: Not necessarily the one who knows patient care, who knows the security of—

Ms. Deborah Hammons: I don't know in this instance. My assumption would be they would be experts.

M^{me} France Gélinas: That's good.

The Chair (Mr. Ernie Hardeman): Okay. The government side: Mr. Flynn.

Mr. Kevin Daniel Flynn: Thank you, Deborah, thank you, Wayne, for your presentation.

My experience with my LHIN—my riding is Oakville and my LHIN is the Mississauga Halton LHIN. I have a very positive experience with my LHIN. The work that I've seen them undertake I think has really spoken to the value that we hoped LHINs would be able to provide when we went to that system.

What I've specifically seen is the advances they've made in things like off-premise day surgery, ALC days of care. They were able to bring a lot of the mental health providers—we found out that we had a lot of people providing mental health services. The people in the community were having a hard time trying to find those services or were finding the wrong service. They were able to get those people into a room and ask them to look at it through a patient-centred lens and to amalgamate, to go to a lead provider. Things like opioid abuse—they've got plans in place now that are being generated through the LHIN. So I find the consultations that the LHINs have done in my own community have been very, very positive ones. They've worked really well.

I'm wondering, in this case, there appears to be a concern over the quality of a service that was provided in a number of hospitals. I'm looking at this from a quality assurance perspective. What's the best thing that LHINs around the province, and your LHIN specifically, could bring as a positive to this issue? What's the best thing you could do?

Ms. Deborah Hammons: In my view, there are steps being taken right now. The report that Dr. Thiessen is going to be providing and which will be made public will be—he's a very respected individual. I would like to see the recommendations that he brings forward implemented.

Mr. Kevin Daniel Flynn: Do you play a role in that? Do you see yourself as part of the accountability agreements or whatever? In the future, do you see the LHINs playing a role in whatever comes out of this committee? Do you see yourself and your brother and sister LHINs implementing them somehow in their own communities?

Ms. Deborah Hammons: There could be something that comes out of his report that we may have a role in. We want to ensure that the quality of care and safety is maintained across our LHIN. It's important; it's one of our strategic directions. So if we can play a role that would help with this, we'd be more than pleased to do that.

Mr. Kevin Daniel Flynn: Thank you, Mr. Chair.

The Chair (Mr. Ernie Hardeman): Thank you. Does the opposition have any further questions?

Mrs. Christine Elliott: No further questions. Thank you, Chair.

The Chair (Mr. Ernie Hardeman): No further questions. We have one minute left on the time for the third party. Ms. Gélinas.

M^{me} France Gélinas: I'm just going to come back to Ombudsman oversight. Do you know if the Ombudsman has oversight of your LHIN?

Ms. Deborah Hammons: Do they have oversight of our LHIN?

M^{me} France Gélinas: Of your LHIN.

Ms. Deborah Hammons: Like if there's a problem with our LHIN, they would have—

M^{me} France Gélinas: Oversight?

Ms. Deborah Hammons: I'm not aware of that.

M^{me} France Gélinas: I'll let you know that he does, just so that you know. Thank you.

Ms. Deborah Hammons: Thank you.

The Chair (Mr. Ernie Hardeman): That's it? No further questions? That concludes the hearing. You didn't want to use any more of your time? That's very good. That concludes it. We thank you very much for your participation this afternoon.

With that, before we all rush out, the next meeting is tomorrow at 4 o'clock. Anything else for the good of—one of those service clubs—for the good of Rotary? If not, we stand adjourned.

The committee adjourned at 1741.

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Oversight of pharmaceutical
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La surveillance, le contrôle et la
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STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Tuesday 14 May 2013

Mardi 14 mai 2013

*The committee met at 1600 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIES

The Chair (Mr. Ernie Hardeman): I call the meeting of the Standing Committee on Social Policy to order, a study related to the oversight, monitoring and regulation of non-accredited pharmaceutical companies. We have one delegation this afternoon, but prior, before we start, and as they're sitting at the table, I just wanted to clear up a piece of business here.

Yesterday, Ms. Gélinas asked for the electronic records from the—

The Clerk of the Committee (Mr. William Short): It was last week.

The Chair (Mr. Ernie Hardeman): A couple of days ago—the electronic records from the pharmacists from Peterborough—

The Clerk of the Committee (Mr. William Short): The electronic worksheets.

The Chair (Mr. Ernie Hardeman): Yes, the electronic worksheets. They are not available from Peterborough; they go directly to the Lakeridge centre. So we need a clarification of the motion, that we ask for them from the Lakeridge centre rather than through the pharmacist to get them from Lakeridge. If you would make that motion that we get them from Lakeridge.

M^{me} France Gélinas: Given the new information that has been shared with me, I would request that the same request be made of Lakeridge, please.

The Chair (Mr. Ernie Hardeman): Okay. Thank you very much. That also goes with Ms. Jaczek's request. It would be in that same vein. That information would come along with that from Lakeridge.

SOUTH WEST LOCAL HEALTH
INTEGRATION NETWORK

The Chair (Mr. Ernie Hardeman): With that, we have the South West LHIN with us today. Thank you very much for coming out. As with all the others, obviously, we're conducting these committee hearings under oath, so we will ask the Clerk to swear you in and start the process.

The Clerk of the Committee (Mr. William Short): Mr. Barrett, I think you had asked to swear an oath?

Mr. Michael Barrett: That's right.

The Clerk of the Committee (Mr. William Short): The Bible is in front of you there, if you want to just grab it. Thank you.

Mr. Barrett, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Michael Barrett: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Mr. Low, did you want to do the same or did you want to be affirmed?

Mr. Jeffrey Low: The Bible is fine.

The Clerk of the Committee (Mr. William Short): Okay. Mr. Low, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Jeffrey Low: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. Just for the committee's benefit, I would point out that the South West LHIN is the LHIN that covers my riding of Oxford county. So I do appreciate them being here and I do know the gentlemen personally. If I give them the benefit of the doubt any time during the meeting, you'll know that it's to encourage their liking me, too.

With that, as we do with all others, you have 20 minutes to make a presentation to the committee. Then, when you're finished with your presentation, we will have 20 minutes for each party to lay any questions they have about your presentation and your involvement. I think we start with the—

Mr. Jeff Yurek: The NDP.

The Chair (Mr. Ernie Hardeman): —the third party with the questions.

With that, the floor is yours, Mr. Low.

Mr. Jeffrey Low: Thank you very much, Mr. Chair, and good afternoon to everyone. My name is Jeff Low and I'm the board chair of the South West Local Health Integration Network.

I'm here today with Michael Barrett, our chief executive officer of the South West LHIN, and we would like to thank the members of the Standing Committee on

Social Policy for inviting us to appear before you as you undertake the study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

Obviously and firstly, we would like to express our sympathy to the patients and family members who have been impacted by this unfortunate issue. We recognize—I recognize—the significant impact that it has had on these patients and family members, and we regret that they have been subjected to this additional stress and anxiety during an already stressful and anxious period in their lives as they go through chemotherapy treatment.

I myself have been the board chair of the South West LHIN for the past 15 months. When I'm not doing this role, I'm also the director of employer relations at Fanshawe College in London, Ontario. At Fanshawe College I'm responsible for all employee-related issues, including union management relations, recruitment and anything that impacts employee relations per se.

In my past, as well, I've also held a senior human resources position with Citigroup and with Canada Post Corp. across the country. It has been a career of about 40 years, and I'm sorry to say it's getting long in the tooth.

I do know the great strides that our hospitals and our health system undertake to ensure that patients receive high-quality care and how steadfast our health service providers are in working to restore the confidence that Ontarians have in their health care system.

I hope that we're going to be able to address the committee's questions today to assist the committee in fulfilling its mandate with this review.

With this introduction, I'd like to pass it over to Mike Barrett, the chief executive officer of the LHIN, to provide some additional information about our organization and the role that it has played in this situation.

Mr. Michael Barrett: Thank you, Jeff. As Jeff indicated, my name is Michael Barrett. I'm the CEO for the South West LHIN. I'd like to thank the standing committee for taking the time to hear from the South West LHIN about our role within the Ontario health care system.

I have spent the last 13 years in health care, previously working as the manager of planning and support with the southwestern regional office of the Ministry of Health and Long-Term Care in London, as the regional perinatal and pediatric coordinator in southwestern Ontario with the two London hospitals—London Health Sciences Centre and St. Joseph's Health Care, London—and as the business manager for women and children's services at London Health Sciences Centre. I was hired by the South West LHIN as a senior director back in 2007 and was then appointed as the CEO in 2008 by the South West LHIN board of directors.

A bit of background about the LHINs: The 14 LHINs were established in 2005 as a fundamental component of the Ontario government's plan to build a stronger health care system in Ontario. Specifically, LHINs are responsible for planning, integrating and funding the local health system and ensuring accountability of local health service providers, including public and private hospitals,

community care access centres, community support service organizations, mental health and addiction agencies, community health centres and long-term-care homes. The LHINs work closely with—but are not responsible for—the funding of physicians, public health, ambulance services, laboratories and provincial drug programs.

The South West LHIN is one of the larger LHINs, especially in southern Ontario. It covers an area from Long Point in the south up to the Bruce Peninsula in the north. It is home to almost one million people. Our LHIN has a large rural component and includes the counties of Elgin, Oxford, Middlesex, Huron, Perth, Grey and Bruce, and a portion of Norfolk county. Some of the urban centres in our LHIN include London, St. Thomas, Woodstock, Stratford, Goderich, Walkerton and Owen Sound.

Our staff and board work with over 150 health service providers. When I describe health service providers, that includes hospitals, the CCACs and community providers, so that captures the name for all those. Our board makes decisions on investing over \$2.1 billion in health funding each year for our region. Our LHIN includes 20 hospitals on 33 different sites.

As the CEO, I have the responsibility of leading a staff of approximately 40 full-time people, with a small number of contract staff. I provide information, advice and counsel to the South West LHIN board of directors on local health system planning, integration and funding issues. I also provide assurance to the board on the LHIN's compliance with legislative acts, standards and codes, and information about potential risks that may affect operations or viability of the LHIN.

Our annual operational budget—the budget that we have responsibility for for our staff—is \$6.2 million, which means that 99.7% of our funding goes to front-line health service providers.

An important note is that the province of Ontario is one of the last provinces to move to a regionalized health care system. One of the major differences between regional health authorities in other provinces and LHINs in Ontario is the fact that LHINs have maintained local boards of directors for all of the health service providers that are funded by the LHIN. This means that the organizations that we fund all have a board of directors and staff which are responsible for the oversight and leadership of that organization.

The South West LHIN board of directors is composed of nine members, of which Jeff is chair. It meets monthly to make decisions on health system planning, integration and funding issues within our area. Our board meetings move around each month to different communities to ensure that our board has a presence across our LHIN. Our board has met everywhere from Port Rowan in the south to Tobermory in the north. As part of our board meetings, we hold community engagement sessions in those communities following the board meetings to engage the public and board members from the health service providers in that area.

All of our board meetings are open to the public. We post all agenda materials on our website in advance of

the meeting so that they can be reviewed by anyone who has an interest. We almost always have members of the public in attendance, and we will often have members of the media, unions or health interest groups in attendance as well.

Our board members are also actively involved in a number of integration initiatives with health service providers in our LHIN, engaging the board members of these organizations to help advance these sometimes challenging discussions.

The LHINs operate within an accountability framework that is comprised of the Local Health System Integration Act, commonly referred to as LHSIA, passed in March 2006; the memorandum of understanding; and the ministry-LHIN performance agreement, the MLPA.

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LHSIA states that a LHIN is required to enter into a service accountability agreement with each of its health service providers that it funds. So the South West LHIN has service accountability agreements with all of its 150 health service providers. These agreements do not define each and every service or program delivered by the health service provider. Instead, the agreement defines performance expectations related to financial sustainability and key service areas. For hospitals, these areas would include items such as emergency room wait times and joint replacement wait times.

If a hospital identifies that it is not able to meet its levels as outlined in the agreement, notification would be provided to the LHIN, and the LHIN and the hospital would then begin the process of performance improvement.

LHINs do not deliver or provide service to patients, clients or residents. Health service providers have the primary responsibility to deliver services and programs to the people they serve, and the clinical and operational decisions are the responsibility of the health service provider. In keeping with the LHIN mandate to plan, integrate and fund the local health system, LHINs work with health service providers to find ways to strengthen the overall health system to better meet the needs of patients, clients and residents.

LHINs also work to integrate organizations across the health continuum. We work to ensure that hospitals are connecting with long-term-care and community providers, and that community providers are connecting with primary care. Integration means a more efficient and effective system, and that is important when health care costs are increasing and our population is aging.

The LHIN, through our board chair, is accountable to the Ministry of Health and Long-Term Care. Each LHIN has entered into an agreement with the ministry called the ministry-LHIN performance agreement which specifies the LHIN accountabilities on key health system measures. These measures include such items as per cent alternate-level-of-care days, percentage of hospital readmissions and others of those types. LHIN and ministry leadership meet on a monthly basis, and ministry and

LHIN staff meet and talk frequently on various initiatives.

The LHIN also employs physician leads. We have a physician lead who works one day a week in primary care, critical care and emergency departments. These physicians do not provide clinical advice to patients, but rather provide advice and leadership about health system improvements which could be implemented across a wider geography within their respective areas of specialty.

LHSIA also requires that LHINs and health service providers engage their partners and the public. The South West LHIN undertakes extensive community engagement and, as stated previously, incorporates community engagement sessions into our board meetings. The purpose of community engagement is to inform, educate, consult, involve and empower stakeholders in health system planning and decision-making processes to improve the health care system.

I would just like to briefly touch on our involvement with the issue around chemotherapy with a chronology of events.

On the morning of Saturday, March 30, I received a phone call from Gary Switzer, CEO of the Erie St. Clair LHIN, informing me of the situation related to chemotherapy at London Health Sciences Centre and Windsor Regional Hospital. At that time, I was informed that it may include other hospitals, possibly hospitals in Hamilton and in New Brunswick. Gary and I discussed the need for coordination amongst the hospitals.

I immediately contacted the regional vice-president, Cancer Care Ontario and the vice-president at London Health Sciences Centre, Neil Johnson, and left a message. Neil returned my call and we discussed the situation which was unfolding. Neil informed me about the circumstances at LHSC and we discussed the action which LHSC was taking to address this situation.

Neil also indicated that he understood that Cancer Care Ontario had connected with the ministry and minister's office communications people. Neil and I also discussed the need to ensure coordination amongst the affected hospitals.

The following Monday, on April 1, a teleconference was organized by Erie St. Clair LHIN CEO Gary Switzer that I attended with Gary, Debbie Hammons—who is CEO of the Central East LHIN, who appeared yesterday—along with representatives from Cancer Care Ontario, London Health Sciences Centre, Windsor Regional and Lakeridge Health. The call was facilitated by Michael Sherar, Cancer Care Ontario president and CEO. During the call, we discussed an outreach plan to communicate with patients and their families, and the hospitals outlined the steps that they had taken and would be taking to communicate with patients, their families and the community.

On this call, London Health Sciences Centre informed the group that their communications would include phone calls, couriered letters and face-to-face meetings with patients, as well as the set-up of a web page and 1-800

number to answer questions, and engagement of media to ensure people were aware and knew who to contact for more information. In the coming days, news releases and updates were sent to patients and media, and posted on the hospitals' websites.

We relied on London Health Sciences Centre to communicate with the affected patients and their families and would like to thank London Health Sciences Centre for their proactive approach. LHSC provided us with updates of their progress over the coming weeks to keep us informed. The hospitals swiftly addressed the issue, alerted provincial colleagues and collaborated in the development of coordinated communications.

So in summary, the health service providers in the South West LHIN have a long history of collaboration and partnership. This strong system of health service providers ensures that we are working together to address the needs of the residents in our region and ensuring that the appropriate steps are taken when the system faces an unfortunate situation like the one we are talking about today.

I hope we have provided the committee with a better understanding of what the South West LHIN does and our role within the health system. Jeff and I would be pleased to answer any questions the committee may have.

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we'll start with the questions. Ms. Gélinas.

M^{me} France Gélinas: I will start with something that has nothing to do with why you came here today and just let the good people in Tobermory know that the Chi-Cheemaun is going to be running as of Friday morning so that they can come and visit us in northern Ontario on Manitoulin Island. I just thought I would pass it on to the north end of your area.

Interjection.

M^{me} France Gélinas: No kidding.

Mr. Michael Barrett: I was in Owen Sound on Friday, and I saw the Chi-Cheemaun sitting there in the sound, so I'm happy to hear that it's moving.

M^{me} France Gélinas: Yes, it will be moving as of Friday.

All right, back to the issue at hand. You were here yesterday; you heard some of the questions. The questions will be very similar. But just to go through, what do you know about hospital procurement and hospital procurement policies?

Mr. Michael Barrett: We ensure that the hospitals are following the broader public sector procurement guidelines. We ask them to issue a certificate of compliance to us indicating that they have complied with those guidelines. Procurement is the responsibility of the hospitals, and they certify that they are following those guidelines in that certification back to us.

M^{me} France Gélinas: Okay. When it comes to the procurement policy, they deal mainly with value for money, making sure that the process is done in a way that is fair and that provides the best service, goods etc. at the best price. Is there any relationship between yourself and

hospitals that deals with safety? I'm mainly interested in patient safety issues related to procurement.

Mr. Michael Barrett: Again, we rely on the hospitals to ensure that those patient safety issues are contained within the procurement processes they will be implementing. So we would rely on the hospitals to do that.

M^{me} France Gélinas: Okay. And did you know, through one way or another, that there were grey areas of oversight when it came to admixing of drugs?

Mr. Michael Barrett: I did not.

M^{me} France Gélinas: When did you find out?

Mr. Michael Barrett: It was, in small part, on that Saturday when I first received the call and probably in more detail on the Monday, when we had the teleconference with Cancer Care Ontario and the regional cancer programs.

M^{me} France Gélinas: Who told you what?

Mr. Michael Barrett: On the Saturday call with the regional vice-president from London Health Sciences Centre, I heard some of the circumstances surrounding the issue at London Health Sciences Centre. Then on the call on Monday with Cancer Care Ontario and the other hospitals, I heard more detail about how wide the impact of this situation was. I heard a bit about how this situation happened, but I didn't get much more detail at that time. It probably came out over the coming weeks as we started to learn more about it at the LHIN level.

M^{me} France Gélinas: Once you found out that there was a grey area of oversight, was it ever discussed?

Mr. Michael Barrett: What part was ever discussed?

M^{me} France Gélinas: That when it comes to oversight of drug admixture—the chemotherapy drugs that are giving us problems were being mixed off-site in an area that was neither a pharmacy nor a drug manufacturer. They were a part of Marchese Health Solutions. That was not a pharmacy and that was not a manufacturer, so it fell into what we describe as a grey area. Have you had any conversations about this grey area of oversight?

Mr. Michael Barrett: The majority of our conversation has been about ensuring that patients are getting the information that they need around the situation at hand. I don't believe I've had any conversation around the oversight part of the situation with the London Regional Cancer Program.

M^{me} France Gélinas: Did you have this conversation with anybody else, either in-house, with the ministry or with anybody else?

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Mr. Michael Barrett: We have had this conversation internally at the LHIN office, simply to recognize that we're aware that it is an oversight. But we did not have a conversation about what actions we needed to take because we believe that the responsibility for that rests elsewhere within the system, not with the local health integration network.

M^{me} France Gélinas: Do you ever see that responsibility coming to you?

Mr. Michael Barrett: No, because as I said in my opening comments, the responsibilities for clinical ser-

vices and programs rest with the health service providers that we fund. We have a responsibility for system management, and we rely on the staff, leadership and the boards of those local health service providers to deliver on clinical programs.

M^{me} France Gélinas: Okay. Who are the players who should have responsibility for oversight? You've made it clear that it wasn't you, and I agree. Who do you figure the oversight should rest with?

Mr. Michael Barrett: Pharmacy is not our responsibility, so it would be inappropriate for me to guess where the appropriate oversight lies. I would wait to see Dr. Thiessen's report. He would provide the expert advice around where that oversight should exist and be put into place.

M^{me} France Gélinas: If we were to tell you that there was other outsourcing that the hospital did, that was done with unregulated providers, would you get involved?

Mr. Michael Barrett: If that situation existed for a clinical issue, we would not, because again, we rely on the hospitals and other health service providers to deliver on clinical programs and services. That oversight for the clinical programs would be the responsibility of, in this case, hospitals.

M^{me} France Gélinas: So it's clear in your mind that the responsibility doesn't rest with you and shouldn't.

Mr. Michael Barrett: Correct.

M^{me} France Gélinas: Okay. Has your LHIN ever had any discussion internally with the ministry stakeholder partners about outsourcing of health care programs and services? Let's take outpatient physiotherapy being divested from one of your hospitals and going into the community. Have you ever had conversations about divesting of programs and services that used to be provided by one of your partners and are not anymore?

Mr. Michael Barrett: Yes, we would. We have the responsibility for managing the accountability agreements for all of our health service providers. If a health service provider is looking at closing a program or shifting a program out to a community, that's where our responsibility comes into play: to ensure that if there is a program that is going to be closed—what is the impact? Is it going to impact the community sector? Is it going to impact another hospital? That's where the LHIN would play a role in that system management.

M^{me} France Gélinas: Could you give me a concrete example of this, where a program was divested from one of your hospitals, and how you managed that?

Mr. Michael Barrett: One example that comes out clearly for me happened a couple of years ago, as we were working with hospitals and looking at ensuring that hospitals can get to a balanced position. One of the hospitals was looking at actually closing their obstetrics department—one of our small hospitals. Our board carefully considered that to determine, is it appropriate, for one, because maybe the program would be better delivered elsewhere; but if the program is going to be delivered elsewhere, the resources also have to move with it. If they're no longer going to be providing that

service and it would be appropriate, then the resources would have to go to another organization that would be doing those deliveries.

In the end, the hospital never went through with that. It was a discussion with us and, through our conversations, the program is still operating soundly at that hospital. That's one example of the types of conversations that we have about program changes within the system.

M^{me} France Gélinas: Could you give me an example of a program change where the hospital ended up not providing that service anymore?

Mr. Michael Barrett: I think when the LHINs first took over responsibility for managing the accountability agreements and ensuring we were getting to a balanced position, several hospitals looked at closing what we call complex continuing care beds. Complex continuing care beds are a type of bed within the hospital; in that case, they were closing the beds to ensure they could get to a balanced position. They felt they could close them, based on the fact that the occupancy was down and they were no longer needed. So in those circumstances, the beds ultimately did close and left that hospital, which received the support of our board because, from a health system perspective, the beds were no longer required. It was appropriate that we'd have a reduction of that nature.

M^{me} France Gélinas: Okay. When it comes to handling those discussions where there will be a change in the programs and services, could you talk to me about your community engagement? I'm interested in seeing what happens when the community has a different opinion as to what program and service change is being proposed.

Mr. Michael Barrett: Any changes within the health care system often generate interest from local communities. We have had examples where there have been community groups, or members of the community within a particular community, that have raised concerns. In those circumstances, they've been able to attend our board meetings and to hear the deliberations of our board.

In some circumstances, our board has actually gone to the second extent of meeting with that group to talk about the issue at hand. If they were concerned about a particular change to a hospital or a program, our board has, on several occasions, met with those members of the community to hear their concerns. What we found is that the community wants to be heard. If the decisions are being made in Toronto or being made by a board that's not listening, that's when they get concerned. In these circumstances, the community groups had the opportunity to sit face to face with our board members to make some of those decisions.

M^{me} France Gélinas: You touch, in your presentation, on the issue of trust. I think it was you, Mr. Chair, who congratulated the front-line care workers for rebuilding that trust. Is this something that your LHINs are involved with? Is your LHIN involved in trying to rebuild the trust that was shaken up?

Mr. Michael Barrett: Do you want me to answer?

M^{me} France Gélinas: Either one.

Mr. Michael Barrett: Yes, because we need to ensure that people have trust in every part of the health care system, whether it's in hospitals, primary care or community care. Situations like this, unfortunately, start to erode that trust.

What we need to do is communicate all the benefits that the health care system provides to them on a day-to-day basis, and some of the positives that all of their health service providers have done over the last number of years; focus on the positive to ensure that we reinforce the good things that happen within the Ontario health care system.

M^{me} France G  linas: For people who were not directly affected—that is, they wouldn't have gotten a phone call but their trust was shaken nevertheless because they heard about it or they knew someone, but they don't get the one-on-one reassurance that was afforded to the people directly—how are you handling that part?

Mr. Michael Barrett: I'm very familiar with that because that has been a question that's been posed of me in my position—people who weren't directly affected by the issue at hand but had a relative who may have been. The hospitals have done a good job of communicating what they've done to address this issue, to explain how it happened, and ensure that steps are being taken to address it.

I think committees like this today ensure that the issue is being taken seriously within the province and that there will be actions to address it, so hopefully it doesn't happen again.

M^{me} France G  linas: Do you feel that the number of complaints to your agency has increased because of it?

Mr. Michael Barrett: I can't say that it has.

M^{me} France G  linas: No? Have any of the complaints come to you, to the LHINs?

Mr. Michael Barrett: No. I'm not aware of any calls coming to us from the public. The majority of the concerns directed to the hospital are being addressed by the hospital through the—they've held, at least in London, a number of public sessions to try and address the concerns that have been raised.

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M^{me} France G  linas: For people who have had their trust shaken up toward the hospital, have lost trust with the London Health Sciences Centre and would like an independent voice to investigate, they are asking for Ombudsman oversight. They want an independent third party to give them answers, rather than somebody in whom they don't have a whole lot of trust right now, although I agree with you that they are trying to rebuild. What are your views on that?

Mr. Michael Barrett: In the South West LHIN, and I can probably speak on behalf of my 13 colleague LHINs as well, a principle for us is transparency. The more people who know about how decisions were made, how we got to that decision point—transparency ensures that people understand it. They may not agree with the final outcome, but at least they understand how we got there. I would have no concerns about increasing the level of

transparency about any component of the work that we do.

LHINs take an extended effort; we make sure that we are as transparent as possible with all of our decisions in our board meetings, as I said in my opening statement. I don't think that transparency is a bad thing within the health care system, so that people understand how the decisions are being made.

M^{me} France G  linas: Do you think that there will be a role for LHINs to play in preventing that type of situation from happening in the future? Do you see a role for your agency?

Mr. Michael Barrett: No. I'd reflect on what I said earlier, that the responsibility for clinical programs and services rests solely with the health services providers. We're not in that business. We have the responsibility for health system management, and if we were to take on those responsibilities, we'd need to be structured in a very different way. We don't even have access to personal health information—legislation prevents us from having that—so we're not the right organization to be having that responsibility.

M^{me} France G  linas: Of the 150 health service providers in your LHIN, are all of them accredited in one way or another?

Mr. Michael Barrett: No. All of our hospitals are. A large majority of our community agencies are, but we also fund on a broad spectrum, from the biggest organizations, like London Health Sciences Centre, down to small organizations that include Meals on Wheels, VON and organizations like that. The smaller organizations typically aren't accredited and haven't gone through that process to complete that.

M^{me} France G  linas: Is this something that you feel would add value to the system?

Mr. Michael Barrett: I think that accreditation is a good thing, to ensure that organizations are looking at themselves and their own processes to ensure compliance with appropriate legislation, best practices and standards. The difficulty is that with small organizations, they have very small budgets, and to take time and resources out of their budget means that those resources are coming out of front-line care. I think there is a balance there in terms of the size of an organization that can actually take on accreditation and get it done.

M^{me} France G  linas: I realize you're not an accreditation expert or anything; where would you draw the bar? In the 150 agencies that you have accountability agreements with, where do you draw the bar as to how small or how big the ones are that are not accredited?

Mr. Michael Barrett: We don't require accreditation through our service accountability agreements. With all the agreements that we have with the 150 health service providers, that is not a requirement. Accreditation is something that those organizations take on themselves to ensure that they're adhering to the proper standards within their own field. I'm not in the best position to say what organizations should or should not. I was explaining earlier about why some do and some don't.

M^{me} France Gélinas: This is rather surprising to me, because when the ministry used to have transfer payment agency agreements, they used to require accreditation, but you don't.

Mr. Michael Barrett: That's correct.

M^{me} France Gélinas: Okay. I'll let it go around.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Mr. Barrett and Mr. Low, for coming. As you know, you are the third LHIN that we've heard from, and your presentation obviously contains many similarities to what we heard yesterday from your colleagues in Erie St. Clair and Central East. However, we always learn something, and there's a little bit of additional information here which perhaps I'll pursue.

But in relation to this incident, in terms of the relationship between you, your fellow LHINs, Cancer Care Ontario—I'm thinking of this phone call that actually occurred when you first heard from Mr. Switzer. How would you describe the interaction between all the players? Could you sort of characterize what the discussion was like?

Mr. Michael Barrett: I think we all recognized the importance and significance of this issue, because the call did not wait until Monday after the weekend was over. We called each other on Saturday. We realized that all the hospitals were dealing with this, and we wanted to ensure that they were working together in a collaborative fashion.

Gary Switzer described this yesterday in his questioning, to state that our role was to allow the hospitals to focus on patients, to ensure that they were getting that information out to the patients who required the information. Our role was to help ensure that there was coordination across the province. So working with Cancer Care Ontario, we were able to do that on the teleconference on that Monday, where we brought all the organizations together to ensure that we had a provincial response to this issue. As we found out on that same day, it was larger than Ontario, as well with a hospital in New Brunswick affected. But our role was to ensure that there was coordination and collaboration amongst the hospitals and the three LHINs that were affected.

Ms. Helena Jaczek: Since then, have you been part of the working group that the ministry has instituted?

Mr. Michael Barrett: We have not.

Ms. Helena Jaczek: You have not. But you feel some of your fellow LHIN colleagues have, I presume—

Mr. Michael Barrett: No, we have not.

Ms. Helena Jaczek: So you have not.

Mr. Michael Barrett: And it comes back to our role to ensure that we're relying on the hospitals to focus on the clinical programs and services, and we stay at the health system management level. So we have not—no LHIN has been involved in the working group that was established between the ministry and hospitals.

Ms. Helena Jaczek: Okay. Now, you, Mr. Barrett, did work originally, or previously, as a manager of planning

and support with the southwestern regional office. Obviously, we all know there were regional offices for many, many years, probably decades. Our government did institute the LHIN structure. Would you be able to sort of give us, from your perspective, some of the pros, maybe some cons, of the new structure, as you have a perfect opportunity to compare the two?

Mr. Michael Barrett: Sure. There were seven regional offices that were structured by the Ministry of Health and Long-Term Care. They had a responsibility for working with the health service providers in the geography that I'm in now. We worked in partnership with the district health councils as well. So district health councils had the responsibility for planning; the regional offices had the responsibility for the operational components of the health care system around flow of funding and things like that.

The major difference between those two organizations—because right now LHINs do planning, funding and integration, so we do everything that those previous offices did. In our geography, there was actually 90 staff within the two DHCs that existed within our area, plus the regional office. You saw, in my opening statement, that we have 40. So there is a significant reduction in the number of staff that are actually doing the same job, and even more with what we do now by actually having the decisions made.

The regional offices had no decision-making power. Now decisions for local health system funding, planning and accountability come to our board. Our board is there in those local communities, whether it's Walkerton, Chesley or Owen Sound, making those decisions in front of the public and the media. Whereas before, decisions typically were made in Toronto, now those decisions are being made locally.

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Ms. Helena Jaczek: So you would say that local is good in terms of the decision-making, and you've been able to achieve some cost savings in terms of administrative costs because you've integrated the DHC with the regional office.

Furthermore, you have those two functions—the planning and the funding—closely linked, so presumably there's some efficiency in terms of approval of the agreements that you have with hospitals and so on, because it's all in one place. Is that fair to say?

Mr. Michael Barrett: That's correct. With district health councils, they did great planning, but they actually couldn't move that planning forward into implementation. They relied on the health service providers that they were involved with—hospitals, community care access centres and community providers—to make those decisions, but they had no power to actually move those planning recommendations forward into change, whereas now we can do the planning, together with our health service provider partners, and our board can make the decisions around changes in the flow of funding and changes in health system services to ensure that those planning recommendations that were sound with the DHCs, those

same recommendations that come to us or that we do now, can be implemented by our board.

Ms. Helena Jaczek: In terms of the administrative costs of your budget, how much for these 40 staff and any other accompanying administrative costs? What type of percentage are we looking at?

Mr. Michael Barrett: Our annual operational budget is \$6.2 million for 40 staff, plus a number of contract staff, and we do receive a number of one-time allocations as well for different items around the physician leads, which I mentioned—the three physicians that we hire. Those come on a one-time funding basis. But our operational budget is \$6.2 million, so that means 99.7% of our money that we receive goes to front-line health service providers.

Ms. Helena Jaczek: To front-line health care, so a very minor cost for the staffing etc.

In terms of your board meetings—this was a little piece that was a little different from what we heard yesterday, and thank you for including that piece—you do have members of the public attend. Are they able, in any way, at any time, to make some sort of deputation or provide feedback that the board might consider?

Mr. Jeffrey Low: We do have many people who attend our board meetings—unions, the general public and the press as well. We don't entertain delegations per se, but as a general rule, if there's someone there who has something they want to say we make room for them to be able to express their opinion.

Ms. Helena Jaczek: You allow them to do that?

Mr. Jeffrey Low: Oh, absolutely.

Ms. Helena Jaczek: Okay, that's very good. In terms of complaints—my colleague from Nickel Belt was talking a little bit about this—does the LHIN receive complaints? As an example, if a patient or family member might have tried to complain to a hospital or one of the agencies for which you are responsible and if they were not satisfied, do they call or can they call? How would you handle it?

Mr. Michael Barrett: We have a process within our office that lays out how patient complaints—or consumer complaints, as we call them—would come into our office. We have one person within our office who has that responsibility to address them.

The complaints can come from a number of different areas. They can come from a physician telling their patient to call the LHIN. They can come from MPP offices. We get calls where "I'm not exactly sure how to address a particular question that comes in," so they call the LHIN.

Typically the questions that we get aren't our responsibility, so if they're clinical programs and services, that type of issue, we'd work with whether it's a hospital or the CCAC, because they have patient relations staff that would help deal with that. So we make that connection for that patient calling in.

Sometimes the questions that come in are around OHIP—issues with their OHIP card, how they're dealing with OHIP. We don't have responsibility for OHIP, but

we ensure that they're connected with the right people within the OHIP office. We create that link between us and the other part of the health care system to make sure that they're directed to the right location. Our philosophy is that they will get an answer or assistance in getting to the right person to talk to about their concern.

Ms. Helena Jaczek: And do you find that that usually resolves the issue, or do you have people phoning back saying, "I'm still not satisfied"?

Mr. Michael Barrett: On the odd occasion, we may get patients, clients or residents who have concerns about the delivery of services. We've done our connection with the health service provider. We feel that everything that could be done has been done to get addressed, and we explain that to the patient, client or resident when they call.

Typically, we will take those complaints and, as I said earlier, get them to the right person to get them addressed.

Ms. Helena Jaczek: In terms of your accountability agreements with the individual health care provider agencies, if you find that perhaps the provider is not responding to your suggestion, say, around wait times, or there is something that you're concerned about: Could you just go through the process of how you handle that?

Mr. Michael Barrett: I think it's a very good indication of how the LHIN system works. When the LHINs first started, we had a number of hospitals with financial challenges. We worked with the hospitals to try to get them to get to a point where they could get to a balanced position. In some cases, we actually appointed a peer reviewer to look at that hospital to determine ways that they could get to that balanced position.

The benefit of the LHIN system is that in some circumstances, the administrations of the two organizations come to a stalemate in terms of how to advance the conversation. This is where board governance and having a board of directors at the health service provider level and at the LHIN level has played a really strong role in advancing some of these conversations that had difficulties to advance. In some circumstances, we've brought in a three-member group of our board to meet with a three-member group of the health service provider board, whether it's a hospital or a community provider. That elevates the conversation above the administrative-type talk that happens with staff. In all those circumstances, having the board governors involved has allowed us to elevate the conversation enough to help to get it over that, as I said, stalemate to advance the conversation. We've had a number of circumstances where we've seen great success in doing that.

Ms. Helena Jaczek: When would you need to contact the Ministry of Health and Long-Term Care if a situation was not resolved? You presumably may have to do something like that.

Mr. Michael Barrett: Typically, we try to resolve the issues at the LHIN level because the accountability agreement is between the LHIN and the health service

provider. It's not between the ministry and the health service provider.

When the ministry becomes involved, it would be in a situation where the ministry does have some responsibility for an issue. The ministry still continues to fund different components of the health care system, so a provider may receive funding from us as well as from the ministry. Not in many circumstances, but it would be in those circumstances where we'd involve the ministry in the conversation to help address it. But we try to resolve it at the LHIN level.

Ms. Helena Jaczek: And as a general rule, you are successful.

Mr. Michael Barrett: We're not perfect, but I think we've had a good track record of success.

Interjection.

Ms. Helena Jaczek: Mr. Low, would you like to fill us in?

Mr. Jeffrey Low: I would definitely say, as a general rule—and Mike has made an excellent point: The advantage of having individual boards with all the health service providers is it provides an extra layer of opportunity to have conversation in a meaningful way on how to resolve issues—take it out of the administration, take it out of the operations into the whole governance perspective. We have board-to-board engagement sessions where we bring together board chairs and members of boards from across the South West as well where we have these types of discussions on a high level, if you will, but in the overall sense of how health care is being provided throughout the South West. It does provide us with a second look, if you will, and I'm a firm believer that the opportunity that has been made here in Ontario to keep boards at the actual health service provider level has been integral to our success.

Ms. Helena Jaczek: That's very interesting, especially in light of Mr. Barrett's comment that other provinces, in fact, did not maintain a board of directors within their regionalization as it occurred. So you both would be firm believers in maintaining that board of directors.

Mr. Jeffrey Low: Yes.

Mr. Michael Barrett: Yes.

Ms. Helena Jaczek: Because actually, this committee is supposed, at some point, to do a review of the LHINs, as you probably know. Hopefully we're going to get some additional information through this most unfortunate process, but it's very helpful to have your input.

I think we'll reserve our time, Mr. Chair, for whatever may happen.

1650

The Chair (Mr. Ernie Hardeman): Okay. Thank you. We'll then go to the official opposition. Ms. McKenna.

Mrs. Jane McKenna: Thank you so much for being here. You were very attentive yesterday, sitting and listening through the whole process. My first question is just for clarification for myself. When we had the hospitals here they came out to say that they were the ones that set up the communications for the direct lines to the oncologists and actually called all of the patients that were

affected by this chemotherapy drug. I'm curious as to what your roles actually were.

Mr. Michael Barrett: Our role is very limited in this conversation. What I said earlier is we wanted to ensure that the hospitals were coordinated in their response because the Erie St. Clair LHIN was hearing what Windsor Regional was doing; we were hearing what London Health Sciences Centre was doing, and we wanted to make sure that we had collaboration and coordination across all hospital sites across the province so that there was one approach to move the response forward. That's why we asked the hospitals to come together on that Monday to have the teleconference to talk about how we can ensure that there is coordination.

Mrs. Jane McKenna: Okay. I was just confused because when they were here they seemed to say that everything was fine with what they were doing and they didn't need anybody else coming in to interject that. I just wanted to know that myself—that other layer that was there.

I have another question here. On what you said today—sorry, there wasn't a page number on it. You say here, about your performance contracts that you have, that if one of them is not met—I just wonder what is the ramification for the hospitals not meeting the performance contracts that they have in front of them?

Mr. Michael Barrett: So in the service accountability agreements that we have, if they're not meeting the indicators or requirements that are outlined in that agreement, we institute what's called a performance improvement process. That performance improvement process is intended to address the deficiency that they may have. It may be financial, it may be something else in terms of wait times, which I mentioned. The performance improvement process around financing: I mentioned earlier that we've had hospitals that have had difficulties getting to a balanced position—this was early on in the LHIN mandate. In three circumstances we appointed a peer reviewer. The peer reviewer went in, compared the cost of that hospital to other comparable hospitals across the province. Ultimately, at the end of that process, we got those three hospitals to a balanced position.

Another circumstance around wait times would be cancer surgery wait times. Our cancer surgery wait times in the South West LHIN have been the worst in the province for the last six years. We've taken significant action to get that number down. We've now dropped it from just under 100 days down to 59 days. We've made significant progress, but it's ensuring that each hospital is addressing that cancer surgery wait time within their own organization—making sure they have the right data, making sure they have the right processes in place to get the cancer surgery wait time down.

In both those circumstances, if there was one area that they were deficient on, we would meet with the hospital to target that area to try to get them to the area that would meet the requirements of the agreement.

Mrs. Jane McKenna: What specifically would you do to have such a drastic drop, to get them to those wait times? I'm just curious of what that would be.

Mr. Michael Barrett: With the cancer surgery wait times, we implemented a project called the cancer surgery improvement project across the South West LHIN, co-chaired by two of our hospital CEOs, together with a cancer surgeon within our geography. They looked at clinical pathways to ensure that we were addressing the time that it took for the patient to get from the referral to actually getting the surgery completed, and what were the delays in that process.

Pulling that apart, they were able to identify efficiencies within that pathway to reduce the time it would take from the specialist's consultation to the time the surgery took place. That was done in a number of different aspects—in this case, it was urology surgery. That allowed us to get to a lower wait time.

The other piece was around data analysis: If we had people waiting on the wait-list for cancer surgery, how long have they been waiting for? Is it their own choice that they're not going through with the surgery? They may be going to Florida or someplace south, not wanting the surgery right away. So doing a deeper dive on the data to figure out whether the wait times that are showing up on our data analysis are actually clear and concise around what's happening with the patients themselves. There are a number of different components that we took to try to address that.

Mrs. Jane McKenna: When you've set up those parameters for what you're achieving, does the Minister of Health and Long-Term Care look over that to make sure that all the checks and balances are in order, or is that from your level? Where does that level come from?

Mr. Michael Barrett: The only connection we'd have with the Ministry of Health and Long-Term Care would be—we have a performance agreement with the ministry. The ministry says, "We want the South West LHIN wait time for cancer surgery to be a certain number of days." That's what we call our target. Our target is typically below what our current performance is. Then it's our responsibility to figure out all the different steps that we need to take locally to try to address, to get the number down to the target that was agreed to with the ministry. The ministry sets the target, and then we look to adhere to that through the local processes that I described.

Mrs. Jane McKenna: Okay, thank you very much. That's it for me.

The Chair (Mr. Ernie Hardeman): Mr. Yurek?

Mr. Jeff Yurek: Thanks, guys, for coming up. I have a couple of questions for you. I've been asking everyone—the College of Pharmacists seems to be okay with the suggestion, and the hospital association kind of wasn't in agreement with it yesterday: What are your thoughts on the College of Pharmacists overseeing hospital pharmacies?

Mr. Michael Barrett: As I said earlier, that issue is well outside the scope of our responsibility, and I'd be

hesitant to give any input or advice around what the appropriate tack would be with their involvement.

Mr. Jeff Yurek: With regard to procuring compounded or admixed mixtures, has the Ministry of Health ever discussed with you setting up a procurement guideline for that process outside of the BPS?

Mr. Michael Barrett: No.

Mr. Jeff Yurek: No? I know that that area has been grey for a number of years, and we've heard testimony that the Ministry of Health has known about this for quite some time now. Wouldn't you think they would have given you guys a call to maybe review the procurement process that hospitals are undertaking, perhaps, in this area, and since it is a grey area and they don't know who's regulating who or overseeing what, that maybe they would have taken the lead and let the LHINs take the lead in the area and direct the hospitals to review their processes?

Mr. Michael Barrett: No, because the ministry wouldn't look to us to provide advice to hospitals around clinical services and programs. They rely on the hospitals to undertake that. We do not have the expertise or the skills within the South West LHIN to address those types of issues—

Mr. Jeff Yurek: But this isn't really a clinical skill or process. It's a procurement, like the BPS, which I think falls short on—especially when they know there's a grey area present, do you not think that maybe that would have been a direction to maybe lead the LHINs on?

Mr. Michael Barrett: I don't disagree with the fact that it needs to be addressed, but we're not the organization to address that.

Mr. Jeff Yurek: Okay. That's it.

The Chair (Mr. Ernie Hardeman): Okay?

Mr. Jeff Yurek: Okay. Thanks.

The Chair (Mr. Ernie Hardeman): Ms. Gélinas?

M^{me} France Gélinas: I have 60 seconds left so I'll use them wisely. The RNAO put out this idea that the contracts that the CCAC has with home care providers look very similar to the contracts you have with some of the smaller providers you talked about, such as Meals on Wheels. Has the LHIN ever looked at being the one who has contracts with the home care providers rather than the CCAC?

Mr. Michael Barrett: No, and as my colleague indicated yesterday, we don't have responsibilities for front-line service, whereas the providers that we fund, including the CCAC, do. That's why we rely on them, whether it's the CCAC or hospitals, to undertake that process, and it's not something that we would get involved with.

M^{me} France Gélinas: But a contract with Bayshore is no different than a contract with Meals on Wheels.

The Chair (Mr. Ernie Hardeman): Go ahead and answer that question.

M^{me} France Gélinas: A contract with Bayshore is no different than a contract with Meals on Wheels. What's the difference?

Mr. Michael Barrett: Well, the CCAC has the responsibility for providing that front-line service, whereas

LHINs ensure that the providers that we fund are providing the—we rely on the hospitals, the CCAC and other providers that we fund to deliver front-line service. It's not our organization.

M^{me} France Gélinas: So you see a difference—

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Jaczek?

1700

Ms. Helena Jaczek: Since we have you here, I'd like to ask you a little bit more about your LHIN and the role that you play in Ontario's health care system.

First of all, you have a very large number of providers—I think it was 150 or so. Is that a reasonable size for you in terms of the geography of your LHIN, in terms of sort of the span of control, your ability to manage those accountability agreements?

Mr. Michael Barrett: It is a large number of providers, but you have to look at how the providers interact with each other. We have a large academic health sciences centre, a teaching hospital in London, and referrals come from the geography that we have responsibilities for, from Owen Sound to the north, and up from St. Thomas and Tillsonburg from the south.

It is a large number—very challenging, with the number of staff that we have—but I think it's certainly a size that's manageable with our responsibility, because we're not providing that front-line care; we're providing health system management, ensuring that those 20 hospitals and the 150 organizations are working together in a comprehensive network of care.

Interjections.

Ms. Helena Jaczek: Mr. Chair, I'm finding the side conversations really distracting.

Mrs. Jane McKenna: Sorry.

Ms. Helena Jaczek: I'm sorry, Mr. Barrett. If you could continue.

The Chair (Mr. Ernie Hardeman): If we could keep the sound down at the far end—if we could keep the tone down so we can have the discussion here that's going on the record.

Ms. Helena Jaczek: Thank you.

Mr. Michael Barrett: I pretty much concluded. It's a large geography. From end to end, it takes us about six hours to drive from north to south. The 150 health service providers is large. But as I said, that group, plus—my colleague from Erie St. Clair mentioned this yesterday. The Erie St. Clair LHIN and the South West LHIN function as a very close network because of the referrals into London. There are a lot of referrals that come in from Chatham and Sarnia, which are outside of our LHIN. But I think we ensure that the providers that we have responsibility for are working together in networks.

The one other piece that I'll add is, within our geography, because it's rather long from north to south, we do a lot of work in Grey-Bruce, the collection of providers there, within Huron-Perth—there's a collection there—and then within the Thames Valley area, which was Oxford-Elgin and London-Middlesex, to ensure that those

providers are working together in a more comprehensive network across their geographies.

Where it works for a smaller geography, we will pull them together. In a larger geography, we also do a lot of initiatives across the full breadth of the LHIN.

Ms. Helena Jaczek: So you've been able to manage the challenges, and you feel you're functioning in an appropriate way that provides for quality care across your LHIN?

Mr. Michael Barrett: Yes. You can slice the province a number of different ways in terms of the delivery of health care services and health system management. There are proposals out to have smaller groups of health service providers coming together, which I think again is very helpful within a small community, to have all providers across the sector working together.

Again, I think what we're doing is working. It's not to say that it's perfect, and I'm happy to talk about that in the next—when we talk about the legislation that will be coming before this committee.

Ms. Helena Jaczek: And in terms of the responsibilities of the LHIN, as currently constituted: Would you say that you feel they're appropriate? Is there any other function that you would be interested in taking on, or something that you would prefer to divest yourselves of? Could you just flesh that out for me, please?

Mr. Michael Barrett: For me, it's very clear that primary care needs to be brought into the fold. Primary care is the foundation of the entire health care system, and right now it's not as well-connected as it could be with our hospital community mental health and addictions partners. We've taken strides to bring them into the mix. With the appointment of a primary care lead, we now have a primary care network. But we need to ensure that primary care is better connected with the rest of the system. I think they'd admit that as well, and we've been trying to do that.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes your time. Any further questions from the official opposition?

Mr. Jeff Yurek: We're good.

The Chair (Mr. Ernie Hardeman): No further questions? Then we thank you very much for making your presentation this afternoon and for answering our questions.

As I was sitting here listening, it was very interesting, but I notice that there was not much in the questioning that had to do with the challenges we're facing with the chemotherapy. I guess that's because maybe their connection to the LHIN is not quite as acute as it is to some of the other people we've been meeting with. But we thank you very much for being here to answer the questions that were put to you.

Mr. Michael Barrett: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. With that—yes?

Mr. Jeff Yurek: Chair, just further to the stability data received today, it raises a new issue. Would we be able to request from Baxter and Marchese their stability

data on gemcitabine and cyclophosphamide? Is that possible?

Interjection.

The Chair (Mr. Ernie Hardeman): The Clerk says yes. Do you want to make a formal request for that?

Mr. Jeff Yurek: I would like a formal request for the stability data that they use.

Ms. Helena Jaczek: In relation to refrigeration?

Mr. Jeff Yurek: If you read that data, it kind of goes, “Uh-oh, what’s going on here?” They’ll probably have their own data that they have, but let’s just get it on the table.

The Chair (Mr. Ernie Hardeman): Okay. Yes, Ms. Gélinas?

M^{me} France Gélinas: I don’t think that this is the right time, but I’d like to go through the list of other witnesses that have been called and if any scheduling has been done.

The Chair (Mr. Ernie Hardeman): We have two more scheduled presently. We can give those names now, if the Clerk would just tell the committee.

The Clerk of the Committee (Mr. William Short): For the Monday following const week, which is May 27, Jake Thiessen, I believe, is scheduled for that day. We were waiting for confirmation from another group, which we have not received yet, along with the new name of the pharmacy assistant that we just received from Lakeridge DRCC, I believe.

On the Tuesday, it’s the Ontario chemical producers, I believe it was—the group that had actually emailed in asking to present before the group. I’m not sure if I have the right name of the association, but it was the chemical producers’ association, something along those lines, that are scheduled for the Tuesday. That’s where we stand right now.

The Chair (Mr. Ernie Hardeman): Have you got any further names that have yet to be scheduled that have been asked by the committee to appear?

The Clerk of the Committee (Mr. William Short): The one other pharmacy assistant from Peterborough health, which we haven’t scheduled yet, which we’re waiting for the Monday, depending on—I think the preference was for the Lakeridge one before the other Peterborough one. If I stand corrected, the subcommittee can meet and change that preference, but that was the information I had so far.

M^{me} France Gélinas: When is our next subcommittee meeting?

The Clerk of the Committee (Mr. William Short): Whenever you guys want to call one.

M^{me} France Gélinas: Given the list of names that we have received, I would ask that we sit down and look at them together and see who we want to call next. I think that could be useful.

The Clerk of the Committee (Mr. William Short): Yes, that’s fine. I’ll arrange one through the Chair.

M^{me} France Gélinas: When Medbuy went out on their RFP, they told us that three companies responded to their RFP. We got a graph as to how the three companies scored on their scoresheet, but we never really received the actual proposals that I’m guessing the companies had sent in. I’m sure they didn’t send it in already in a graph by their criteria. There has to be a document that led to what we got. It seems like we’re missing a part, or maybe I’m missing a part; that happens too.

The Clerk of the Committee (Mr. William Short): I believe that Medbuy is planning on tabling something with us as early as tomorrow which may include what you’re talking about right now.

M^{me} France Gélinas: Very good.

The Chair (Mr. Ernie Hardeman): Okay? Ms. McKenna?

Mrs. Jane McKenna: Can we find out who owns Medbuy, what corporation owns it?

The Clerk of the Committee (Mr. William Short): Yes.

The Chair (Mr. Ernie Hardeman): Yes, that can be done. I think that’s very important. I think it might be helpful for the committee, not only who owns Medbuy but what the Medbuy entity actually is. I think we heard some testimony in the committee that the directors were representatives of hospitals, but we also heard in testimony that the contract does include money coming back to the hospital over the purchase. I think it would be interesting to know if some of the money that goes to Medbuy is also part of the activity as to a refund to the hospital in the process of buying through that avenue. I think it would be helpful to the committee if we got the particulars of the structure of Medbuy.

M^{me} France Gélinas: Their website has some of that information, as to who are the member hospitals and that kind of stuff, but there’s no harm in asking them to provide it to the committee.

The Chair (Mr. Ernie Hardeman): Okay. Anything else? If not, we stand adjourned until Monday, May 27.

The committee adjourned at 1710.

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Monday 27 May 2013

Standing Committee on Social Policy

Oversight of pharmaceutical
companies



Journal des débats (Hansard)

Lundi 27 mai 2013

Comité permanent de la politique sociale

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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 27 May 2013

Lundi 27 mai 2013

*The committee met at 1409 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIES

The Chair (Mr. Ernie Hardeman): I call the committee on social policy to order. We're meeting here for a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

DR. JAKE THIESSEN

The Chair (Mr. Ernie Hardeman): Our first deputation this afternoon is Dr. Jake Thiessen. Before we do that, we will point out that, first of all, after today's—we only have two delegations we will be hearing, and hopefully we'll have an issue of a report that we'd like to discuss after that. Hopefully the committee will be able to stay after the two to hear that.

Secondly, I just want to point out that as with all delegations, we will present you with 20 minutes to make your presentation. At the end of the presentation, we will have 20 minutes of questions from all three parties to ask any questions about your presentation that they may have. We will start the questioning this time with the government caucus.

With that, Doctor, thank you very much for coming in and sharing your knowledge and your successes or failures with us. We do have to swear an oath to this committee at this time, so with that, we'll turn it over to the Clerk for the swearing of the oath, or affirming your oath.

The Clerk of the Committee (Mr. William Short): Dr. Thiessen, do you prefer to do an oath or an affirmation?

Dr. Jake Thiessen: Oath.

The Clerk of the Committee (Mr. William Short): Oath? Okay. If you just want to grab the Bible, please. Thank you.

Dr. Thiessen, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Dr. Jake Thiessen: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for that. Now we will turn the floor over to you for your presentation.

Dr. Jake Thiessen: Thank you. Good afternoon. I've come to inform you a bit about the work that I've been doing as an appointed independent reviewer for the entire oncology medication issue.

I thought perhaps I'd give you a little bit of background about myself. I'm originally from Manitoba. My first degree in pharmacy was from that university. Ultimately, I went to the University of California, where I obtained a PhD, particularly in medicinal chemistry. I'm a former professor, associate dean and current professor emeritus at the Leslie Dan Faculty of Pharmacy. In fact, I used to walk across in front of Queen's Park on a regular basis.

Following 33 years at the University of Toronto, I spent six years at the University of Waterloo, where I had strategic responsibility for the development of a new health sciences campus and Canada's 10th school of pharmacy. Education, research and administrative leadership have been central to my academic career for about 40 years.

I am specialized in an area that—the words may be foreign to you—pharmacokinetics and pharmacodynamics, which basically describe quantitatively those forces that affect how the body disposes of or handles medicines and how, in turn, medicines affect the body. The dynamic of these two areas influences strategies around patient treatment in all disease states.

I've spent some years working with medical oncologists and basic scientists at Princess Margaret Hospital. In recent years, my University of Waterloo research collaborations explored a special region of light and its illuminating benefits in the pharmaceutical and medical fields. I can tell you that we have a start-up company that was formed called Verisanté, which is traded on the ventures exchange. Our first product, called Aura, is a revolutionary technology allowing skin irregularities to be scanned and thereby assist in the early diagnosis of skin cancer.

My broad experience includes international projects in countries like Taiwan, Saudi Arabia, Sudan, Nigeria and others, actually. I've been the president of the Canadian Council for Accreditation of Pharmacy Programs. In a past life, I chaired the Ontario Ministry of Health's Drug Quality and Therapeutics Committee. I chaired the Health Canada Scientific Advisory Committee on Bio-availability and Bioequivalence. Presently, I serve Health Canada in the capacity as chair of the Scientific Advisory

Committee on Pharmaceutical Sciences and Clinical Pharmacology.

I suppose, on the basis of my qualifications and experience, I would be considered seasoned with a broad understanding of professional education, research methodologies, pharmaceuticals, the industry surrounding all of that—supply chain, patient care etc.

On a more personal note, my interests in cancer include not only the areas that I've mentioned, but my own father passed away prematurely from the illness. My mother also had a severe bout of it, and my wife's two sisters have died of cancer.

When I was asked whether I would take on this role of independent reviewer, I was reminded of Martin Luther's comment, which was, "Our lives begin to end the day we become silent about the things that matter." This kind of riveting idea was what actually helped, in some ways, in agreeing to do this.

My official appointment date is identified there as April 15, and this is some three and a half weeks following the first discovery of the questionable products. Regarding the details of the appointment, I suppose you're familiar with them, and so I'll pass over those in the interest of time.

As I approached all of this, I thought that trustworthy insights are gained through evidence-based information and validation. So I was very keen to make sure that whatever information I gathered was not just hearsay but evidence-based. I have approached this incident without a preconceived bias regarding stakeholder guilt or innocence.

In terms of methodology, I put this down as the combination of the Kipling method and root cause analysis. Kipling is what we widely know as what, why, when, how, where and who—those kinds of things. This is a fundamental kind of research approach. Research that involves root cause analysis also has a similar kind of flavour to it.

To assist with informing you today, I thought it might be helpful to present two figures that encompass this incident and the stakeholders. So on page 3 of the hand-out, I present first what I call kind of the directly linked stakeholders around the incident. They, of course, are the vendor and the group purchasing organization, which in this case is Medbuy. There are materials I will refer to later on that really link the vendor and the GPO. There are, of course, the hospitals, and ultimately there are the patients.

On the following page, page 4, I am presenting to you what I call an enlarged group of key professional, structural, regulatory and oversight stakeholders. You can see that this encompasses the Ministry of Health for Ontario, Health Canada, the Ontario College of Pharmacists, Cancer Care Ontario and the Ontario Hospital Association, and then there are a series of others that one might say certainly have strong professional interest in this entire development. As I speak to this later on, I will refer to these two figures.

As a caveat, I want to alert you to the fact that my work is still not complete. You've asked me to appear as

I approach the midpoint of the 13.5-week allotted investigation time. Some aspects remain to be explored, and the final recommendations are not yet formulated. Nonetheless, I seek to distill for you in a short period of time some of the key things that I feel have emerged as part of this six-week journey I have been making.

In view of the dire implications for patients—and I can tell you that that was the heartbeat for why I got into this. It was all about trying to figure out—given my own experiences in my own family, it was all about patients. I even told the minister directly that the only reason I was interested in this was to pursue the patient care issue. I was simply wanting to somehow try to gather information about the incident and substantiate the evidence and its outcomes. It was important, I felt, to learn how the episode had been dealt with, as this incident was not only about materials—it's not only about chemotherapeutic agents—it's about people who had been affected.

To begin with, as I've indicated there, I felt it was necessary to begin at ground zero, which in this case is the Peterborough hospital where the discovery was made on March 20. Remember, I was appointed officially as of April 15, so I launched very quickly into the work before me, which was to try to gather the information. As you'll see here, April 17 was the date for the visit to Peterborough, and Lakeridge was actually included at that same time.

The New Brunswick institutions were eventually contacted as well, and I did that via telephone. Thereafter, the search expanded to stakeholders like the vendor, Marchese, followed by those that would be considered as part of what I've already referred to as the professional or regulatory involvement.

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Beginning at the level of patients, I want to highlight first what happened at the level of the hospitals and then the enlarged group of stakeholders. I'm calling this the "response to the incident" regarding the affected group.

I want to remind you of the numbers which you undoubtedly have heard before, but the best count that I have is 1,202 patients, ranging from only one in Peterborough through the largest number, which is in London, and then ultimately 183 in New Brunswick. That represents the entire count.

One of the quotes that I use in a variety of presentations that I make both nationally and internationally is the one that I picked off a website entitled *Finest Quotes*. It goes like this: "We eat food prepared by others, drive on roads built by others; we rely, every day, [on] actions of others, and we are relied upon in turn. Where trust fails chaos closes in. Our entire civilization relies on a singular faith that we can count on others." I thought to help you a little bit, on the positive side, maybe an overarching outcome that I've observed is to say, "Okay, let's just review this from the point of view of: Was the trust in the institutions that are involved here real and legitimate?" So I thought I would quickly walk you through some of the responses that I've observed.

To begin with, I must tell you that there were absolutely valiant efforts to find the identities of the patients,

sometimes combing through three computer records. You don't know the kinds of efforts some people made in trying to identify the patients. Then I want to tell you that pharmacy—and there's no nepotism here—pharmacy in those institutions took decisive action in removing the questionable items from the supply system. They played a responsible and responsive role here in contacting potential users—and there is no formal structure to this. This is an informal system of passing information on. I actually searched for all of these items that they said had been taken out of the supply system. I wanted to know: Were the counts supported when I saw the quarantined items in the total counts of things that they had purchased or had obtained? So I walked through all of that and I can tell you, every one of them is accounted for.

Not only that, they had an immediate backup plan where they began making in-house both the cyclophosphamide and gemcitabine doses—a terrific story, I feel.

I feel that there was mobilized action on a grand scale. Diligence by administration, risk management personnel etc., was absolutely exemplary. There was uncommon commitment to trying to connect with patients—and you can imagine physicians in their busy role, medical oncologists, who are not only burdened with the customary role of seeing patients, who now were reaching out to the patients who had been affected, trying to talk to them. They had mailings, registered mailings; they had town hall meetings; they had all kinds of things that were done in order to connect with people. I give them high marks for this.

I can tell you that the present infrastructure and collection of personnel within each hospital has met and largely overcome a major challenge. Evidence supports the view that the hospitals performed well in this crisis. Many laudable untold actions by administrators, physicians, pharmacists, nurses etc. have been observed.

This was trust illustrated. You can't legislate such action. The health care system would quickly become dysfunctional with such people. I can tell you, although I'm not finished with all of this, I hope to actually have a chronological record of all of these things in the ultimate report that I'm going to assemble.

As far as the other stakeholders are concerned, with that March 20 discovery, eventually, Cancer Care Ontario notified the ministry on the 28th. There were many things that fell out as a result of all of that.

On April 11, to the best of my knowledge, the ministry assembled a working group of all kinds of people to try to deal, on a daily basis, with whatever information surfaced and to see how they could actually contribute to the resolution of the matter.

On April 2, Cancer Care Ontario and the Ontario Hospital Association provided rapid media announcements.

The Ontario Hospital Association, on the 17th, actually sent out a questionnaire to make sure that everything was going to be taken care of, mitigating any kind of further risk.

The Ministry of Health, on the 19th, announced regulatory changes under the Public Hospitals Act, allowing

17 days of questioning, and there were a number of things that were stipulated as part of that regulation, including the role that pharmacy would play, who was licensed to do these things and so on.

On May 10, the Ontario College of Pharmacists announced an amendment to Ontario regulation 202/94, by adding part IX, "Inspection of drug preparation premises." This provided the college with the authority to inspect these DPPs, as we call them, where pharmacists and pharmacy technicians work or at least are proposing to work. There were also things in that regulation change outlining the parameters, including timelines, of how a member is to notify the college of any current or intended employment, and there are many other things that are part of that. They also made a change to some of the accompanying bylaws.

Health Canada also stepped up to the plate. They provided regulatory direction on the 19th of April involving some stipulated constraints around compounding and admixing of medications. Specifically, there must be three conditions prevailing: It must be done within a hospital; if it's outside a hospital, it must be under the supervision of a provincially licensed pharmacist; and if not that, then functionally, it must fall under the licensing and manufacturing requirements as found in the Food and Drugs Act.

If I step back for a moment and just recollect all the things that happened, I have to say that decisive actions were taken, whether in hospitals or through provincial or national agencies, and featured commendable crisis-stemming leadership. There was a concerted resolve to address the issues squarely and urgently and to avoid any similar incident and therefore safeguard patients' care. Again, in keeping with what I said before, I hope to be able to actually provide a chronological record of what took place.

Let me shift to more of the cold analytical side here, which is about the materials that are part of all of this. To help you, based upon the discoveries that I made, I would like to compare for you what actually happened during the days when the vendor, Marchese, was playing its role versus what happened once Marchese was no longer in the picture so that you could clearly see what's the same and what's different.

In front of you, in step 1, as I've called it, are the two medications in question. There's the cyclophosphamide picture on the left, which is a two-gram vial. Then on the right is the gemcitabine vial, which is also containing two grams of the drug. The first step that is required and is followed by both the hospitals now and Marchese then, is to reconstitute the powder. They use the identical Health Canada-approved drugs in those vials. Those medications were contractually obtained by the group purchasing organization; that's part of the group buy. It didn't matter whether it was Marchese doing it or a hospital subsequently. It's exactly the same material. They used exactly the same technique in reconstituting—and I'll say a little bit more about that in a few moments. And they used the exact volume of the same diluent, which is normal saline,

so exactly the same thing was happening at Marchese as was happening subsequently at the hospitals.

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Let's pick up step number 2. They've reconstituted; they've dissolved the medication that's in those vials. The next step is what happens now at the hospital. At the hospital, a particular dose is prescribed for a patient that's individualized and a required amount of drug is drawn up from the vial. That required volume matches the amount that's required for the ultimate administration to the patient.

What happens is, that amount, that volume, is now diluted into approved normal saline. This is a dilution step for the convenience of administration for the patient, and very often, of course, what happens practically is that these medications are administered via an infusion pump, so that's all part of the system of administering.

What happened when Marchese was doing it is this: They also drew up the entire contents of the same vial and they placed them in the bags. These were saline bags from the GPO's—this is the group purchasing organization—approved supply, which was Hospira, and what they actually did was they took two vials in each case. In the case of cyclophosphamide, they used 100 millilitres for each of the two vials. So they had two vials, 100 millilitres each, and they returned those volumes to those bags. In the case of gemcitabine, they used a 100-millilitre supply of approved normal saline and they would take 50 millilitres of that saline, put it into one of the vials of gemcitabine and 50 into the other one—just like what the hospitals do—and then they would take the dissolved material and put it into the bag again.

So are you with me? What the hospital is doing now was in essence what Marchese was doing at that point, but there are a few differences I want you to be aware of.

First, in terms of the gemcitabine, the story is very simple: It was a nominal 100-millilitre saline bag from which they were drawing. When they had withdrawn the 50 millilitres for each of those vials, in essence the bag should be empty, right? Now they put the dissolved drug back into the bag, so basically the bag now contains the equivalent of two vials, or four grams. The concentration, in theory: four grams per 100 millilitres. We can explore this a little bit more.

For the cyclophosphamide it was a little different, in that there is no 200-millilitre bag of normal saline. There's a 250-millilitre bag. That's the nominal quantity in the 250-millilitre bag. What they did first is they withdrew 50 millilitres from the 250-millilitre bag and discarded it. Now they were left with 200. They took 100 out, dissolved the contents of one cyclophosphamide vial and did the same for the second one. The dissolved contents were now returned to the bag. That's what they did.

Step 3: With Marchese in the supply chain, they basically took those bags that had been furnished by Marchese and they then drew out what was considered to be the dose, just like what they're doing now, a certain volume, and diluted it at the hospital into normal saline for administration to the patient.

I hope that clarifies what's the same and what's different between the two situations.

Further clarification I want to present: Only quality, approved pharmaceutical products and diluents were used. It's best to understand these things in terms of what I'm going to call nominal content, accuracy in content and precision in content. We can explore that later on. There is no evidence of any malicious or deliberate drug-sparing dilution in preparing the bags of cyclophosphamide or gemcitabine by Marchese. But I must tell you, diluent overfill is the issue that is critical in all of this.

In closing, let me just add one more thing here. I want to return to the patients, because that was what I was interested in. I believe there is some work that remains to be done, and I'm going to give you just a snapshot of what I'm interested in: the degree to which there is some variance from what is expected in delivery of the amount of either of those two chemo agents. The big question is, so what? What was the implication for patients? That's the key question.

While I have experience in this field, having worked in it to some degree, I think that the best would be for us to take and get an outside opinion about this, in fact, outside of Ontario—not, can I say, part of the Ontario system. So I'm working with Cancer Care Ontario to actually create an objective, exterior-to-Ontario evaluation of what the implication would be of this kind of underdosing that has been presented. I feel that that would do us all a world of good. I think it would provide the best assurance and confidence for patients that the incident is understood, first of all, and to undergird and perhaps restore some damaged trust that is there.

Ladies and gentleman, those are my opening remarks. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation—very thorough and helpful, I think, in our deliberations. With that, we will start with Ms. Jacek.

Ms. Helena Jacek: Welcome to Queen's Park, Dr. Thiessen. You were talking about walking in front of it, and I recalled my days as a medical student on the fourth floor of the medical sciences building. I spent some summers in the department of pharmacology, so it was just a bit of a flashback for me as well.

I'm going to start where you ended. You do have experience, as you've told us, in pharmacokinetics and pharmacodynamics. You are talking about an external review of the impact on the patients, and I think, from the word go, this is obviously the prime concern, certainly, for those of us in the government. We have heard reassuring words to date from Cancer Care Ontario in terms of their opinion of the impact on patients. Could you just elaborate a little bit on the kind of individual responses there are to medications in terms of pharmacokinetics and metabolism by different individuals? Just to sort of give us a general picture of that.

Dr. Jake Thiessen: Okay, thank you very much. Yes, there's certainly a fairly broad spectrum of responses that

you might expect in people. If you look back at the history of even chemo agents, which we're going to talk about specifically, for quite some time, the idea was that perhaps the use of the largest possible dose would be the way to go. Increasingly, over the last number of years, and particularly, I would say, in the last 10 years, what has emerged is something called personalized medicine. Functionally, there's an increasing interest in finding out what a patient is most sensitive to when it comes to the particular cancer. That sensitivity then serves, among other things, to identify the most logical drugs to use.

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But there's more to the story than that. The cancers are embedded in the body. What is needed, if in fact—and depending upon how that chemo agent is used, the drug has to get to that particular cancer site, and that's not necessarily an automatic, depending upon where it is. So part of the goal is to find a dose that would be most suitable in getting the bloodstream to deliver to that particular site. The individual is then dosed upon some metrics, we commonly call them. One of the metrics that sometimes is used is simple body weight, but in Ontario it's more appropriate to use body surface area as kind of a surrogate of the best estimate as to what the dose is that is going to be needed in a particular patient. So that is typically what is done.

The response can vary rather dramatically. There's a fair bit of variability that is encountered in that. One of that areas that I studied particularly was the myelosuppression and whether there would be more science that could be brought to myelosuppression in order to figure out when the next dose ought to be given. There's a kind of a juggling between art and science in all of this. Ultimately, there are factors like the recovery from myelosuppression, for example, or mucositis or whatever it happens to be, but also there are issues around age that are factored into it. There are issues sometimes over organ function, like kidney and liver and so on. So there's always this kind of modification of science, which is the ideal best, with what is known, to serve the patient. There are variables, frankly, that are important in all of it. I hope that helps to clarify—

Ms. Helena Jaczek: Yes. I think what is hopefully reassuring to the public in general is that while this was an underdosing, the actual critical dose for each individual patient is a best estimate, in essence, of what is appropriate. As some of my constituents have said to me in the last week or so during constituency week, thank heavens it wasn't an overdose, that that potentially could have led to more severe side effects as well. So I think this individual response is a very fascinating area, and I think the idea of following up with that investigation is very interesting.

Now, coming back to the way Marchese interpreted the specifications given to them by Medbuy: I presume you've looked at the way Medbuy had their schedule and how it was described, how they wished the medication to be provided to the hospitals. Do you feel that the way Medbuy put those specs out was a reasonable way of asking for this product?

Dr. Jake Thiessen: Thank you. Can I say that I've yet to visit Medbuy? I'm scheduled to visit them in the beginning of June. That's a very critical visit. There's more to an agreement between a group purchasing organization and a vendor like Marchese than meets the eye. There are specifications that at this point I do not know about, that I have not been able to identify. I certainly know about things that Marchese has told me, but if you recall, one of the things I want to do is validate information. So I want to hear it from Medbuy's side.

Ingredients that fall into this are a clear understanding about nominal content, how it was to be packaged, what was to be on the label—a very critical part, what was to be on the label—what storage conditions should have been and so on. This is a bit of an unusual case because there was a prior vendor, namely Baxter, that had served this community for quite some time, and now there's a hand-off that is taking place, a hand-off from an older vendor to a newer vendor. There are a lot of questions about how that hand-off should have been made, and I'm interested in exploring exactly what the clarifications were.

The real hand-off needs to occur to the end user, which in this case is the pharmacy at the hospitals. The pharmacies are dependent upon a clear understanding of what that product is about. As I'm going to explore that with Medbuy, there are a number of questions that I want to be ironclad about, and that will help me understand a lot of things, not the least of which is, what was the overfill factor in all of this?

Ms. Helena Jaczek: I understand that you have yet to visit Medbuy, but would you have expected Marchese to bring to the attention of the receiving pharmacy at the hospital that there was overfill in the bags?

Dr. Jake Thiessen: I think that's a logical question. Marchese's been very careful to indicate that they were delivering on a required, contractually agreed upon product. That's what they were doing. Their interaction with the hospitals was only as a service agency for those contracted products. Would it have been logical? That's something that I want to explore with Medbuy. Because I think there's a triumvirate that's here, and I need to understand much better what the roles of each should have been.

It's easy for us to blame at this point, but it's important first to understand. I need to understand that from Medbuy's side.

Ms. Helena Jaczek: In terms of the rapid response you have outlined to us, it sounds like you were really quite impressed with the individual hospitals, Cancer Care Ontario and the Ministry of Health. Is that a fair summary?

Dr. Jake Thiessen: That's a very fair summary, thank you.

Ms. Helena Jaczek: In terms of the regulations that the Ministry of Health has enacted, do you feel that this is in some measure addressing this gap in oversight that has previously existed?

Dr. Jake Thiessen: Okay. Can I say that I've termed both the steps that have been taken by the ministry and

the activities by the Ontario college as remedial clarification. That's how I've coined it. I think, given everything that unfolded, the importance of making sure that there was no doubt as to who was in charge to make sure that any other vendor or outsource supplier was issuing or providing products that were safe was the right thing to do, these kinds of announcements.

Will there be a broader look at all of this? That's my responsibility. I personally feel that there are some areas here that warrant some further attention.

Ms. Helena Jaczek: With your experience in pharmacy, as you've detailed to us, were you aware of this grey area, grey zone that we've heard about in terms of this lack of oversight of compounded medications?

Dr. Jake Thiessen: You know, I know that's the terminology that is used, a "grey zone." This area of what I would call broadly the professional area of a profession's life is something that is common in many areas. It's not only pharmacy; it's in medicine and dentistry. The United States has also grappled similarly with this whole thing. There is this sense of entrusting to the professionals things that the professionals know most about.

I have never felt this is particularly grey—this is a personal opinion. I felt this is part of the customary evolution of service that professionals provide. Does that necessarily offer the security that we all would like? Well, perhaps not. But you know what? We can fix some of these things and hopefully embed them for future generations.

Ms. Helena Jaczek: You're undertaking the study here in Ontario. Are you aware of differences, province to province, in terms of oversight of hospital pharmacy or of this type of compounding facility? Further to that, would you ideally see a national system so that your findings could potentially affect other provinces?

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Dr. Jake Thiessen: First of all, to your latter point: Yes, I think there are areas of all of this that are of national interest. I mean, it so happened—can we step back for a moment? It so happened that this was Ontario-centric, and New Brunswick was in some ways the recipient of all of this, right? It could have easily been done in New Brunswick, and then, "So how would this look in Ontario," right? I personally feel that there are some national things that need to be looked at.

We have done some work to try to find out what the best practices are in other areas—not only in Canada, but south of the border—and those will be part of the quest as I try to provide the best advice in the future. Thank you.

Ms. Helena Jaczek: We'll reserve any time we have for the next round.

The Chair (Mr. Ernie Hardeman): Thank you. The official opposition: Ms. McKenna.

Mrs. Jane McKenna: Thank you again, Dr. Thiessen, for coming in. Just because we've obviously been sitting here through all of the people that have come in, I'll be

anxious after you speak to Medbuy as to what your—hopefully you'll be able to come back and tell us that.

I have a few questions. When we had Ms. Zaffiro in here, she said that she did exactly what the contract told her to do. When I'm looking at Medbuy, which is a broker—I'm assuming that if somebody is a broker, they understand the product that they are getting and understand the product that they're handing off to somebody else. So I guess my biggest confusion—maybe you can't answer because you haven't spoken to them, but they explained to us that they didn't think that there was anybody else there who did what Baxter did, which was the admixing, so they didn't even put an RFP out. Marchese actually came to them and told them that they could do the job, so nevertheless, they went out to see Marchese's facilities and whatever.

When they had Baxter, they had a contract that they did themselves. We asked if anybody else overlooked that contract that was done, and they said no; they were fully responsible for the contract between them and Marchese and them and Baxter. So I guess my question is, if you're doing the exact same thing with the exact same contract, how can it be different?

Dr. Jake Thiessen: In terms of this, one of the places that I am still to visit is Baxter. I want to understand, also, exactly what happened while they were still offering their services prior to Marchese. There are some elements of that that need to be understood, and you've got to remember that cyclophosphamide is actually coming from Baxter. So ironically, the agency, the vendor, that was both providing a service and a product also now was providing some things to Marchese, so there are some things in that that I am going to be exploring.

Why isn't it exactly the same? If we can use that as the jump-off point. I understand—but this remains to be tested with Medbuy—that in fact Marchese was not privy to the methods and the formulation, if I can call it that, the admixture formulation that Baxter was using.

Mrs. Jane McKenna: Okay. Now that we all realize that, and thank you so much for that, I guess the bottom line is that if you don't know of any other company out there that is doing this, to have them come in and take over this position to do this—I was just overwhelmed, I guess, at the fact that there was nobody overseeing anything, considering that this was a brand new contract with a company that had never done it before.

I'll be grateful, when you do actually go, to see how that fell apart from one company to the next, because clearly—Baxter had that position three years ago in 2010, and they understood exactly what they had to do. So I'm kind of confused with that.

My next question is, should the hospital not at any time notice the extra in each bag after they withdrew the portion from it for over a year? They were doing the same thing.

Dr. Jake Thiessen: I'm sorry, at the level of the hospital?

Mrs. Jane McKenna: Yes.

Dr. Jake Thiessen: Correct. The events that take place inside a hospital—and I've reviewed all of this,

because I've visited them all. I know exactly what happens at every one of the hospital pharmacies. I know how the patients are linked into it all. There are places—especially somebody like London, which is a very busy location—that are preparing hundreds of doses every day. When those bags are there and they are drawing out a certain volume, the idea of them not noticing that in fact there was some residual volume left and so on is entirely obvious to me. Because you've got to remember that there is now in every one of those bags four grams. Well, four grams is not an amount ever given, I don't think, to a single patient. It represents something for a variety of patients. And you get different sizes, as we were talking about a few moments ago. They'll take out several—perhaps 50, 60, 80 millilitres or whatever it happens to be—and there's some left, and it's easily possible not to notice that in fact there's a volume differential. I actually did a test on myself. What I did was I thought, "Okay, everybody thinks that they can tell volume differences." So I had an independent person—this is the scientist in me; sorry—making up 210 and 220 millilitres of saline in a bag. Let me tell you that these bags are irregular. They're squishy. It is very difficult to tell which bags have a variance in the volume that's there. I'm just giving you a practicality of life.

Combining the two things—that is, the nature of bags and the fact that only partial volumes would be drawn out, especially if there were children involved that were being treated etc.—it's entirely possible that they wouldn't notice.

Mrs. Jane McKenna: Just one more thing: Now that everything is back in the hospital and they're doing all the premixing there, each place that came in told us that it was all running smoothly, and there weren't any bumps or hurdles or anything at all. I guess my question would be, what would have been the reason for sending that out, then, if nobody has noticed anything at all by now doing it in-house?

Dr. Jake Thiessen: There are, I think, two reasons for it. One is that it takes a while, particularly for cyclophosphamide, to dissolve. How long does it take? Well, if you were to have an automatic shaker, you could probably get it to dissolve in something like five to 10 minutes. But the way they actually do it is, in the morning, they will decide, during a slow time, to actually create so many vials of cyclophosphamide, for example, and they will add the diluent to it. And then while they're doing other things, somebody comes by and shakes it. Then they'll do something and they'll come by and shake it. So I said, "Well, using your technique, how long does it take?" They said, "About four hours." So if you're a fairly busy place and you're trying to, as that stuff dissolves—to have an agency come along and actually provide you with the dissolved material is a big advantage to them.

The other thing is, they're also working with chemo agents that are noxious under the best of circumstances. To have somebody doing it under what is called USP 797, which is fairly tightly controlled, really nice facilities, makes some sense. But you're asking an important

question: Should it have stayed in-hospital? There are hospitals that do it; they do it regularly. But there was a feeling that it might benefit them in their operation, and that's why they did it.

Mrs. Jane McKenna: That's it for me. Thank you. Go ahead, Jeff.

The Chair (Mr. Ernie Hardeman): Mr. Yurek.

Mr. Jeff Yurek: Good afternoon.

Dr. Jake Thiessen: Good to see you.

Mr. Jeff Yurek: Good to see you. Sorry I was a little late. I was doing a tour with some constituents and we got hung up on the third floor.

I was doing a calculation: It's been 18 years since I sat in your class, so thanks very much. Thanks for doing what you're doing.

Ms. Cindy Forster: You haven't aged at all.

Mr. Jeff Yurek: Oh, thanks.

Dr. Jake Thiessen: He looks younger now than then.

Mr. Jeff Yurek: But thanks very much for leading this study and for the education you've done for all the pharmacists through all the years, both at Toronto and at Waterloo—although I was pro-Toronto, I will say good for Waterloo.

Dr. Jake Thiessen: Oh, that's fine.

Mr. Jeff Yurek: I wanted to ask a lot of questions about Medbuy, but that's fine; I can throw in a few of those. I'll get back to the Medbuy issues.

Just to go off of Jane's question with regard to the hospital, have there been any chemo spills at all since they've taken over? Have there been any issues of that sort?

Dr. Jake Thiessen: To my knowledge, no. That's the best I can tell you.

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Mr. Jeff Yurek: Another question we had: Do you have the stability data? Have you looked at the stability data—

Dr. Jake Thiessen: Yes.

Mr. Jeff Yurek: —because we're having trouble finding data that actually would cover both Baxter and Marchese with supplying the drug for the long term.

Dr. Jake Thiessen: Of the two agents, I would say that cyclophosphamide is the most unstable. At room temperature, of those reconstituted vials, the shelf life is thought to be only four days at most. There's the view that perhaps that ought to be narrowed a bit, depending upon the temperature of these rooms. But if it's refrigerated, then in fact it's something in the order of approaching a month. It's like 27, 28 days for both of them.

One of the things that the people at Peterborough noticed was not only the difference in the label but also the storage conditions. I know that there's been some concern about that whole issue. The view, as you know, Mr. Yurek, is that any time you can prolong shelf life, the better, and simply refrigerating things is the logical thing. So there is no issue for me about the difference in storage conditions. It's that when you refrigerate it, it's better for everything.

Mr. Jeff Yurek: Okay. I liked your point about the hand-off of the contract; that's something that definitely needs to be looked at, to ensure that—continuity of care, I guess, for the patient at the end of the day is what needs to be looked at.

The other question I have is with regard to the College of Pharmacists. You've talked to them. They've been here talking a few times and I've mentioned to them extending the college's powers to oversee and regulate hospital pharmacies, in-house pharmacies. Do you have any thoughts on that?

Dr. Jake Thiessen: Well, you know very well that there is this issue about what the college actually oversees. Hospitals have typically been the jurisdiction of the Ontario Hospital Association, the entire Accreditation Canada matter. I would say that, by and large, pharmacists in these hospitals of course are licensed with the college in their respective locations, and I think—is it right?—something like five out of the 13 areas in Canada do have licensing requirements of their hospital pharmacies by the colleges. So I think that leaves eight that do not have that.

Am I sensitive to that? Personally not, but I could see a standardization as being important, and if it goes that direction, I would support it. Do I feel that it's absolutely necessary? The answer is no, I think it has functioned well outside of that.

Mr. Jeff Yurek: Okay. I'm just going to reorganize my Medbuy thoughts, so I'll pass it on.

The Chair (Mr. Ernie Hardeman): Okay, very good. The third party: Ms. Forster?

Ms. Cindy Forster: Thank you, Dr. Thiessen, for being here today and for your opening remarks about the reasons that you actually undertook this investigation, that the main reason, of course, was for patient care.

My first question is, how was it that you were contacted, recommended, and by whom, to actually undertake this investigation?

Dr. Jake Thiessen: Thank you. I don't know.

Ms. Cindy Forster: You don't know. Okay.

Dr. Jake Thiessen: Very simple. I don't know, and I haven't asked.

Ms. Cindy Forster: So that's a question for someone else.

I'm just going to ask you a couple of specific questions, and then I'm actually going to turn it over to my colleague, because she has a long list of questions and wasn't here for part of your presentation.

With respect to the issue of the stability, you spoke to four days of stability on the cyclophosphamide, but what about the other drug if it's not refrigerated?

Dr. Jake Thiessen: Yes. I guess the standards that have been adopted for gemcitabine is that refrigeration is there, as needed. Is it that there's exaggerated degradation if left at room temperature? I haven't been able to get that information myself, to be honest, but what we know about thermodynamics—and sorry to be technical about it—is that any time you leave it at room temperature, it goes off much more quickly. It's like our butter.

Ms. Cindy Forster: So is that going to be part of the next few weeks when you're actually consulting experts in other provinces with respect to the report you're going to do? Are you going to be delving into that a little further?

Dr. Jake Thiessen: Well, it would be a side issue. But it isn't—dare I say—central to my concerns, because typically, when these things are reconstituted, they tend to be used fairly quickly anyhow; if for no other reason, those vials, reconstituted, serve an immediate need for the patients in the particular unit. With all due respect, it's probably not a primary issue.

Ms. Cindy Forster: Okay. Do you think that a red flag should have been raised at Marchese with respect to the specific concentration versus just mixing this bag as a one-dose, one-patient in light of the fact that it was four grams, and we're hearing from you, and we've heard from others over the past few weeks, that a four-gram dose would not be a usual dose for any cancer patient?

Dr. Jake Thiessen: That's a very reasonable question. It remains for me, and I ask you to accept this, that I need to understand the contractual agreement. That is so critical in all of this. I'm just going to give you some ifs, okay? If in fact there was contentment at the group purchasing agency to leave it at nominal content—and there's a difference between nominal content and accuracy and all these kinds of things—then that makes good sense why they just left it at that. If, on the other hand, there was carelessness or whatever, then that needs to be addressed. At this point, I simply don't know.

Ms. Cindy Forster: Okay, thank you. There was just one more thing. When you were going through your comparison between what happens in hospitals and what happened at Marchese, you talked about the cyclophosphamide being in the 200-millilitre bag, but the bag starts out being a 250-millilitre bag, so they were withdrawing 50 millilitres, discarding that, I guess, and then reconstituting 100 millilitres in each of the two vials. After they discarded the 50 millilitres, would they not have seen that there were still millilitres left, overfill, in that 250-millilitre bag?

Dr. Jake Thiessen: Yes. I mean, that makes good sense, in terms of these vials don't necessarily only allow you to add 100 millilitres.

Ms. Cindy Forster: Right.

Dr. Jake Thiessen: And it would have been rather easy for them, because they're reconstituting what they think is 200 millilitres left, to simply kind of take out enough to reconstitute in the vial and so on. Remember, what they're doing is returning the drug to the bag, right? I asked them specifically about that. They said, "Yes, we did notice always some additional amount or volume left in the bags, but it was never anything severe or exaggerated." To that point, one of the things I've wanted to know is specifically what kind of limits there were for the manufacturers of the normal saline for those bags.

I've got back data from Hospira, which was the supplier in this case to Marchese through the Medbuy agreement. Their US division—let me add one more piece. I

asked for the very lots that I know Marchese was using, so I could actually find the batches and I could now ask their division. What I got back from them is that for the 250-millilitre bag, which is the one that's primarily in question, it was around 8.2%. Their finished product testing was 8.2%, which was, in a 250-millilitre bag, about 20 millilitres more. So that is the error that is there due to overfill, or—can I say—that is the additional amount that's there. Those are the numbers that they were willing to give me back on all of that. I'm discovering that Baxter has the same kind of issue with their bags. Everybody seems to be overfilling.

The question is, should this be, was this, considered in the contract? I don't know at this point.

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Ms. Cindy Forster: You may not know the answer to this either. When Baxter was preparing their medication, though, were they estimating that there was an 8% overfill, or were they actually drawing up the fluid in that bag and basing their 38 milligrams per millilitre on an accurate amount of solution?

Dr. Jake Thiessen: Good question. I will find out when I visit Baxter.

Ms. Cindy Forster: Okay. My last question is, is there anyone else working with you on a team for this investigation. If there is, who are they?

Dr. Jake Thiessen: I am largely independent, resolutely independent. There is some support I get through the ministry with some scheduling and a little bit of literature search, but basically this is a one-man operation.

Ms. Cindy Forster: Thank you very much.

The Chair (Mr. Ernie Hardeman): Ms. Gélinas.

M^{me} France Gélinas: It's a pleasure to meet you, Dr. Thiessen. I'm sorry that I was late. You may have covered this, but just in case: You made it clear that you're halfway through your investigation; 13 and a half weeks is what you were referring to. How long after the 13 and a half weeks have passed do you expect your report to be ready?

Dr. Jake Thiessen: I like delivering on time. July 12 is D-Day.

M^{me} France Gélinas: Okay. So this is what you're going for?

Dr. Jake Thiessen: Yes.

M^{me} France Gélinas: Okay. Good to hear.

I also wanted to know, in the document you gave us, on page 8, you talk about nominal content, accuracy in content and precision in content. I take it that this is the type of terminology that is taught and used in pharmacy?

Dr. Jake Thiessen: Yes, those are rather critical terms. Nominal content is what a manufacturer declares as the target for content for a particular product. If you go into your pharmacy and buy some ibuprofen, it will say 200 milligrams on it, for example. That is the target amount in that particular container. But what actually happens is, when they do finished product testing, that content may not be exactly 200 milligrams, on average. It may be less or more by a certain amount. But more

importantly, there will also be a certain amount of variability that is observed, so not all tablets are necessarily 200 milligrams. They range through a permitted spectrum. The standard for most pharmaceutical products in Canada is plus or minus 10%, which means that while most of the medications will have an amount near the nominal statement that's on the container, there can be some variability around all of that—

M^{me} France Gélinas: Sorry; does the 10% also apply to chemotherapy drugs?

Dr. Jake Thiessen: Okay, I'm coming to that. That's exactly correct: This also applies to cyclophosphamide and gemcitabine. Those vials that are received from the manufacturer are said to have a nominal content—two grams, let's say. What they actually contain is some variation on the theme. Yes, they tend to be around that, but they don't necessarily have exactly 2,000 milligrams, or two grams, in there. There is some spread that is recognized or permitted.

That helps us to understand the idea of accuracy. The precision is how much spread there tends to be. Nominal is what is said to be the target.

Now, let's go to the bags. For the bags, the target on the bag is what the manufacturer says is supposed to be there. In the case of a 250-millilitre bag, it says, "250 millilitres normal saline." The interesting thing is that the permitted accuracy allows it to be higher, and there is still a variability around all of that.

Going to the chemo agents in those vials, at this point, I know about gemcitabine because it comes through a distributor in Canada, but it is actually made off-shore; that drug comes from off-shore. I do not yet know about cyclophosphamide. It is actually distributed by Baxter, and I'm going to try to find out exactly what their specifications are. For the other one, I kind of know what they are. But if one follows what is called the United States Pharmacopeia for both of these, cyclophosphamide is allowed a plus or minus 10% for those vials; for gemcitabine, the USP standard is plus or minus 5%.

M^{me} France Gélinas: So when we're told that Baxter put the concentration amount on their label, is this what you would call precision in content? I'm trying to relate the two.

Dr. Jake Thiessen: The four grams per 100 millilitres is the target; it's the nominal amount. What Baxter did was they actually indicated that in the reconstitution, there was a volume enlargement due to the presence of the drug, which expanded the volume from 100 to 105. They used a bit of a different technique in creating their dosage forms than Marchese did. My understanding, to be affirmed when I visit Baxter, is that they actually started with empty bags.

M^{me} France Gélinas: And built it up from—

Dr. Jake Thiessen: And then filled into them, correct.

M^{me} France Gélinas: Okay. Something that is outside of the purview of what we do, but I was hoping maybe you would look at, is when the technician came and alerted us that he used to get the cyclo drug at room temperature, and his first surprise was that he had to get

it out of the fridge when it came from the new supplier. It kind of raised alarm bells a little bit that, given the short lifespan of those drugs, was there a mistake there from before? How can we guarantee that Baxter was delivering and being used, given that their supply chain was at room temperature, within the four days? It has nothing to do with what we're looking at, but it still worries me.

Dr. Jake Thiessen: Thank you. Good point, something I'm going to be asking Baxter about, because I want to know the full details of their specifications.

In terms of the Marchese side of this, I asked them about this. Why? Because I knew the same kind of issue over room temperature versus refrigeration. Their statement to me was, "When we shipped these things and so on, we felt that a constant environment for both of them was the best way to make sure the right thing was being done." So they basically were asking for refrigeration for both of them, and it was more almost a quality control consistency than it was trying to somehow signal a differentiation. That's the point that they were making. But like I said, to return to the issue, is there something here that needs to be understood from the Baxter side?

M^{me} France Gélinas: So you will be looking at the time lapse between the drug being prepared at Baxter and the drug being used in Ontario cancer treatment centres. You will be looking at that timeline?

Dr. Jake Thiessen: I simply want to know what their specifications are and what the evidence around that is, yes. So if they're saying that four days at room temperature is acceptable, I want to know what their evidence is for that.

M^{me} France Gélinas: Okay. Sounds good.

I want to go away a little bit from the technical nature of what you do more to the human side of what you do. So far, of the people that you've mentioned you've talked to, how did it go?

Dr. Jake Thiessen: How did it go with these people?

M^{me} France Gélinas: Yes.

Dr. Jake Thiessen: It was always a very collegial, open kind of event. Let me just give you a glimpse—can I give you a glimpse into a hospital visit, for example, just to help you understand?

M^{me} France Gélinas: Sure.

Dr. Jack Thiessen: Typically, the arrangements would be made to visit. The first part of the visit would typically be Q&A—question and answer—around a variety of issues. I had a whole battery of questions for everybody in those hospitals, and the people that would be present would be like the president and CEO, risk management people, oncology heads; there would be the pharmacy people, nursing and so on. So the room would generally be filled. It would be a number not unlike this, for example.

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I would pursue everything from infrastructure through how they actually dealt with the news and what the evidence was. Sometimes somebody would say, "Well, this," and I'd say, "Okay, would you please let me know

what your take on all of this was?" So it was kind of, dare I call it, an inquest into the events there.

When all my questioning would be finished, which would be in the hour-and-a-half range, typically, as what we've seen here, I would then make a visit to the places that might have been touched by the medication. Certainly I visited the pharmacies and looked at everything there.

My technique in these places—and it was there or Marchese whatever—was to use a chaser technology, or chaser technique, I should call it, where I would simply say, "Okay, now, I want to know exactly this. Suppose the order comes in here. What do you actually do?" So I'd track everything that was happening, and I could see where there would be areas, issues in hospitals that ought to be addressed, ultimately.

I've been doing this kind of thing with every single visit, so I have a swath of information. That just gives you an idea.

The Chair (Mr. Ernie Hardeman): Just one little question left, and your time is up.

M^{me} France Gélinas: Okay. On a scale of things, you talked about how hard it was to dissolve cyclophosphamide: If you have a shaker, 10 minutes; if you don't—if you know cancer drugs in general that are being mixed in Ontario hospitals, on a scale of 0 to 10 or whatever makes sense to you, how complicated was it to mix those drugs compared to the other arsenals of drugs that are being prepared every day?

Dr. Jake Thiessen: I would say cyclophosphamide is somewhat of an exception. Most of them are used as what we would call salts; gemcitabine is a hydrochloride salt. They dissolve very quickly; they dissolve willingly. But cyclophosphamide is an exception.

M^{me} France Gélinas: Harder?

Dr. Jake Thiessen: Yes.

M^{me} France Gélinas: All right.

The Chair (Mr. Ernie Hardeman): Very good. Thank you very much. Back to the government side: Ms. Jaczek.

Ms. Helena Jaczek: I just wanted to go into the whole concept of group purchasing of these compounded facilities a bit, because my colleague from the NDP has talked through these hearings a little bit about how every extra step and every other organization involved is, in fact, sort of increasing the risk for something to go wrong.

I know you haven't visited Medbuy yet, but in theory, if the concentration is clearly on the specification, if the compound is very clearly labelled as to the concentration, would there be any additional risk?

Dr. Jake Thiessen: Additional risk, please? In—

Ms. Helena Jaczek: In potentially an error occurring. It sounds like there was sort of a bit of a lack of communication that was going on between what Marchese was doing, because they weren't alerting anyone to the overfill in the bag. If they had done what we think Baxter did, which was label according to concentration, where's the extra risk?

Dr. Jake Thiessen: Okay. In terms of the risk, yes, I agree with you completely that every time you add a step, in theory you add risk. On the counter side, the one thing that happens with a group purchasing agreement like this and a vendor like this is you tend to create uniformity, a uniformity in production of something. It's no different than a pharmaceutical company or whatever: Uniformity has some advantages. This is part of what has been widely recognized in hospitals, that when you have many hands doing many things, you also have a risk of some kind.

The other thing is that if you have—and we could perhaps disagree on risk here when it comes to an agency like Baxter or Marchese, but they have the finest facilities. All I can tell you is, in visiting Marchese—I still have to visit Baxter—there is no hospital that I've ever seen in all the visits I've made that has a facility that matches this. It is splendid in its configuration, in all the things that they have as checks and balances. They have some very detailed requirements around how things are produced.

There's a risk in adding a layer, which is a vendor, but there are also some benefits potentially. So one has to weigh this. I think this is a decision that a group purchasing agent needs to make. Sorry.

Ms. Helena Jaczek: Thank you for that.

The Chair (Mr. Ernie Hardeman): Thank you very much. The official opposition, Mr. Yurek.

Mr. Jeff Yurek: A question that just came up, before I go back to my Medbuy questions: When you were visiting the hospital, did you come across any process that staff could undertake if they were unhappy with a product that Medbuy had procured for them?

Dr. Jake Thiessen: Help me again, please, here.

Mr. Jeff Yurek: The London Health Sciences pharmacists said they weren't happy with the label. Is there any process in place at the hospital level to say, "I'm not happy with this product. How do I get a hold of Medbuy and let them know that I'm unhappy with it?"

Dr. Jake Thiessen: You know what? That's an exceedingly good point. In fact I think this speaks to the whole GPO issue, how this unfolds and how hand-off is done and how servicing occurs. This is one of the things, frankly, Mr. Yurek, that I want to investigate with all of them. Was there a way of people declaring some concerns about things? At this point I haven't found it yet.

I understand that one of the reasons why this particular vendor gained the contract was, in fact, the label. They liked the label, ironically—this is the team that was doing the evaluation—so were there some issues over the label at some of the hospitals? There were primarily over the lack of concentration identified and the storage differences. Those were the two things. Was that something that they gave feedback on? I don't know.

Mr. Jeff Yurek: Some of my concerns have been the fact that admixed products are kind of a step up from your average products you procure for the hospital, and my fear is it has just been swept into the big realm of their BPS policy—I guess that's the right name, broader

public sector policy. I feel like a lot of these mixed drugs are now being treated much like ordering masks or brooms or whatever for the hospital. I've looked at the contract from Medbuy, and I know you will; I don't know if you have or not. But looking at risk prevention—and there's a lot of people out there who are a lot smarter and getting paid a lot more at the hospital level than I'll ever be—wouldn't you think it would be easy to limit the amount of risk so that it would actually be specific on the product you want to procure? For instance, we all know there's extra fluid in all IV bags; that's common knowledge in the industry. Wouldn't it be easier just to say we want cyclophosphamide 40 milligrams per millilitre, instead of four grams in 100 millilitres? That way it takes the whole error of overdilution or underdilution—either way—out of the mix.

Dr. Jake Thiessen: I completely agree with you.

Mr. Jeff Yurek: I just hope you take a look at this. Hopefully, you're going to review the RFP process. I think they were new at this for admixtures. There might have been steps. The vagueness of the contract—I think there were a lot of assumptions that were built into the contract, and those assumptions could add failure to every level of any organization or government.

Dr. Jake Thiessen: As we say, Mr. Yurek, the devil is in the details.

Mr. Jeff Yurek: Those are just my two cents I wanted to throw at you as you go forward to Medbuy. Again, I appreciate what you're doing for this province.

Dr. Jake Thiessen: Thank you so much.

The Chair (Mr. Ernie Hardeman): Thank you. Does that conclude the—

Mr. Jeff Yurek: I'm finished.

The Chair (Mr. Ernie Hardeman): If you're done, everyone's done. Thank you very much for your participation in this hearing this afternoon and taking the time out of your busy schedule. I want to say, since we're somewhat in the same exercise, we wish you well in your endeavours.

Dr. Jake Thiessen: Thank you.

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MS. SARAH HICKEY

The Chair (Mr. Ernie Hardeman): Our next delegation is Sarah Hickey.

Interjection.

The Chair (Mr. Ernie Hardeman): If we could ask the people who want to have a conference at the back to please take it out into the hall, particularly Mr. Yurek.

Thank you very much, Ms. Hickey, for being here this afternoon to help us with our process here. As we did with the previous delegations, we will provide you with the opportunity to make a presentation for 20 minutes, and at the conclusion of the presentation we will have questions from each caucus for 20 minutes. This time the questioning will start with the official opposition. With that, thank you very much again for being here, and the floor is yours.

Interjection.

The Chair (Mr. Ernie Hardeman): Oh, excuse me. I almost missed it. We do ask if you would swear the oath. We are doing the testimony under oath, so the Clerk will either administer the oath or have you affirm.

The Clerk of the Committee (Mr. William Short): Ms. Hickey, would you prefer an oath or an affirmation?

Ms. Sarah Hickey: An oath, please.

The Clerk of the Committee (Mr. William Short): The Bible is in front of you there. Ms. Hickey, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Sarah Hickey: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for that, and with that, the floor is now yours.

Ms. Sarah Hickey: Good afternoon, and thank you for inviting me to appear before this committee. I appreciate being given the opportunity to participate in the work this committee is doing.

I'd like to begin by telling you a little about me, and then I will outline my involvement around the events of March 20 and the discovery of the situation involving two chemotherapy medications.

I am a graduate of Dalhousie University, where I obtained a bachelor of science in pharmacy in 1996. Following that, I moved to Toronto where I did a hospital pharmacy residency at Mount Sinai Hospital. I then worked for four years as a pharmacist at what was then called the Greater Niagara General Hospital in Niagara Falls. It is now part of the Niagara Health System.

In 2001, I moved back to Nova Scotia, where I worked as a pharmacist for Annapolis Valley Health from 2001 to 2007. I was also a member of the occupational health and safety committee and the Baby-Friendly committee while I was there.

In 2007, my family moved to Peterborough, and I began work as a hospital pharmacist at the Peterborough Regional Health Centre. I was a member of the medication reconciliation implementation team at PRHC, and I am currently a member of the ISMP ambulatory care medication reconciliation working group representing ambulatory oncology.

In 2010, I became a casual part-time employee of Peterborough Regional Health Centre and took a full-time position as an oncology pharmacist for the R.S. McLaughlin Durham Regional Cancer Centre, which is part of Lakeridge Health in Oshawa.

I have received specialized training in quality improvement implementation, and I am a member of the Cancer Care Ontario regional systemic therapy program safety collaborative. I am a preceptor for the University of Toronto faculty of pharmacy and have been a preceptor for Dalhousie University College of Pharmacy.

I am a member of the Canadian association of pharmacists in oncology and the Ontario Pharmacists' Association,

and I am registered with the Ontario College of Pharmacists in good standing.

Although I am an employee of Lakeridge Health, I work at the Peterborough Regional Health Centre in the cancer clinic. That clinic is a partner of the Central East Regional Cancer Program. I work in the multidisciplinary room, alongside oncologists, nurses and other health professionals. I do some patient counselling and also work with the interdisciplinary team on processing chemotherapy orders. I review the physician's orders to double-check that it's the right drug, the right dose, and whether any modifications should be made based on the patient's individual status, blood work, organ function etc.

I am also asked to research drug information questions for the health care team and check to make sure a patient's home medications do not interact with their chemotherapy.

So that's a little bit about me and my qualifications and experience. Now I would like to address the events of March 20, 2013.

You have heard from Craig Woudsma and Judy Turner, two of my colleagues in Peterborough. As they outlined in their appearance earlier this month, Craig had questions about the label on the Marchese-supplied gemcitabine product.

That afternoon, Craig called me to say there is a new product that looks different than the product that had been in use before. He outlined that the labelling was different. He thought, according to the labelling, that the concentration may be different than what the worksheet indicated.

After speaking with Craig, I called my colleagues at Lakeridge Health to see what they were doing about this difference. We had a discussion and it was concluded that the pharmacy team there would investigate the difference.

I then went to the Peterborough pharmacy and spoke with Judy. As she outlined in her appearance earlier this month, she called Marchese, and I was present for that call.

At first, we spoke with a Marchese representative who did not understand what our concerns were. As Judy noted, he then transferred us to another Marchese representative whose name I cannot recall. She explained how Marchese prepared the product, which was different than how our previous supplier prepared the product. We asked if Marchese had taken into account the overfill in the bag, and she said that they had not.

We concluded that they did not seem to have an appreciation for how we were using the bag or why the concentration was important.

Following that discussion, I did a calculation of the concentration based on our estimate of the contents of the bag. We knew the gemcitabine was mixed in a Hospira bag. We also knew that with a 100-millilitre Hospira bag, there is an approximate overfill of seven millilitres. Based on that, the approximate concentration would have been around 37.4 milligrams per millilitre, compared to 38 milligrams per millilitre, the concentration that was used to calculate the dose indicated on the worksheet.

In that moment, we had to make a decision. We had a patient who was there and needed medication. Based on my experience, I concluded the difference between 37.4 milligrams per millilitre and 38 milligrams per millilitre was not clinically significant.

When dealing with chemotherapy, there are a number of factors that go into the determination of a dose. Factors include weight change, managing side effects etc. For example, if a person's weight does not change by more than 10% between treatments, then it would be acceptable not to alter the dose of medication.

In this specific situation, we did not have any doubt as to the safety of the product. We knew it was the correct drug and we knew it was not a stronger concentration of medication in the product. While I would not normally make a change to the dose, even that small, I believe in the circumstances it was the appropriate clinical decision.

I advised to go ahead with this dose for the specific patient. The alternative would have been to send the patient home without treatment, which would have interrupted that individual's treatment cycle and, in my opinion, been of greater clinical significance.

Later that afternoon, we did receive a call back from the Lakeridge Health pharmacy, and they advised us not to use the Marchese products any further.

I became a pharmacist because I've always had an interest in the sciences, and I wanted to be in a profession that helps people. I grew up volunteering in my local hospital and was always inspired by the health care professionals I met. I chose hospital-based practice because I loved the multidisciplinary team approach, as well as the opportunity to give back to the public system.

I pursued the oncology field because, like a lot of us, someone in my life was affected by cancer. I was always very impressed with the quality of service offered by the cancer clinic and the team of professionals that dedicate themselves to patients with this terrible disease.

I take great pride in my work because I know what can happen when errors are made.

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I am a mom of five children, ranging from my oldest, who is 12, to my youngest, twins who are almost two. Every time I make a decision, I have in my mind that the person receiving the medication is someone's child, someone's parent, someone's family. I am motivated by the fact that we can keep making safety improvements to guard against human error. It is extremely rewarding to use your passion, knowledge and skills every day to help people.

I would also like to state how proud I am of the pharmacy assistants at the Peterborough cancer clinic and what a privilege it is to work with them.

Thank you again for the opportunity to be here today, and I am happy to answer any of your questions to the best of my ability.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. With that, we'll start the questions with the official opposition. Ms. McKenna.

Mrs. Jane McKenna: Thank you so much for coming in here today. I know it can be a bit overwhelming coming in here with everybody speaking and asking you questions. Your presentation was very well put together, so thank you for that. I'm very impressed that you're a mother of five and you look this great, with 12 and under to twins.

Anyway, my first question is, now that you're doing it in-house, have you had any chemo spills?

Ms. Sarah Hickey: No.

Mrs. Jane McKenna: No. Okay. Do you know if there is a process out there at all where people can complain about the Medbuy process?

Ms. Sarah Hickey: I'm not aware of a process, no.

Mrs. Jane McKenna: Okay. On page 3 here—I guess what I'm curious with is, how did you know—what was the difference that you saw or, pardon me, Judy saw from the one product, the Baxter product I'm guessing, to the Marchese product? What was the difference she saw?

Ms. Sarah Hickey: The Baxter product was clearly labelled 38 milligrams per millilitre concentration. On the Marchese label, it said four grams in 100 millilitres.

Mrs. Jane McKenna: I guess we're trying to figure that out, that if it was the exact same contract and there was nothing changing at all—I think we're still trying to figure out how the labels weren't exactly the same from one product to the next, if it was the exact same contract going in the RFP.

When you asked Marchese if they had taken into account the overfill in the bag, she said that they had not?

Ms. Sarah Hickey: Right. She went over the process of how they prepared the bag, and it didn't account for the overfill. Their assumption was we would be using the full bag, so the exact concentration wouldn't have mattered.

Mrs. Jane McKenna: Yes, we had Ms. Zaffiro in here who stated the exact same thing, that a lot of assumptions—you know, if you have a contract, it pretty much stipulates from line to line what exactly the expectations are, from the broker, obviously, getting the product, and then selling that off. They should have known that themselves.

My next question is, later in that afternoon, you said that Lakeridge Health pharmacy advised not to use Marchese products any further. How did they come to that assumption? How did they come up with that to say that, then?

Ms. Sarah Hickey: I'm not sure how they came to that conclusion.

Mrs. Jane McKenna: So you stopped from there?

Ms. Sarah Hickey: Yes.

Mrs. Jane McKenna: Okay. That's it for me right now.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Gélinas.

M^{me} France Gélinas: Thank you so much for coming. I understand that your colleagues came as a pair. It's always a little bit easier. Thank you for being here on your own.

I will go ahead with, first, some of the questions that came from the presentation you just gave. First you said—I'm on page 2, if that helps—"After speaking with Craig, I called my colleagues at Lakeridge Health to see what they were doing about this difference." Who did you talk to at Lakeridge?

Ms. Sarah Hickey: Is it possible that I could give that name to the Clerk?

M^{me} France Gélinas: Why would you want to do that?

Ms. Sarah Hickey: I guess I didn't speak to her about saying her name here, and I don't know if I'm comfortable with that or not. Is it possible to do that?

M^{me} France Gélinas: I think her name has already been shared. We're just double-checking, but I'll respect your wishes.

Ms. Sarah Hickey: Okay.

M^{me} France Gélinas: You will give it to the Clerk after? Okay.

Ms. Sarah Hickey: Sure.

M^{me} France Gélinas: Okay. You went on to say that you spoke with Judy: "As she outlined in her appearance earlier this month, she called Marchese, and I was present for that call," and that particular person "did not understand what our concerns were." Who were you talking to at Marchese at the time?

Ms. Sarah Hickey: I'm not sure what that individual's name was.

M^{me} France Gélinas: Was it a pharmacist?

Ms. Sarah Hickey: I don't think so, but I don't know.

M^{me} France Gélinas: Is there a way you could find out who you talked to?

Ms. Sarah Hickey: Yes, I can find out.

M^{me} France Gélinas: And you'll let us know?

Ms. Sarah Hickey: Yes.

M^{me} France Gélinas: Then you went on to say that you talked to a different representative—the name you don't recall. I wouldn't mind, while you do your research, if you'd try to find out who that person was as well. "She explained how Marchese prepared the product, which was different than how our previous supplier prepared the product." How did you know how Baxter, which was your previous supplier, prepared the product?

Ms. Sarah Hickey: The difference was the Baxter product came in what we call a Viaflex bag, an empty bag that had fluid added to it, and the Marchese product came in a bag that was prepared by Hospira, so it already had a volume in the bag.

M^{me} France Gélinas: So it's not necessarily because you had spoken with Baxter; it's just because you recognized that by the mere fact that they were using a Viaflex bag that they had filled up.

Ms. Sarah Hickey: Right. It was just an observation that there was a difference. I hadn't spoken to anyone at Baxter.

M^{me} France Gélinas: Okay. You go on to say, "We concluded that they did not seem to have an appreciation for how we were using the bag, or why the concentration

was important." I want to hear it in your words: Why was the concentration important?

Ms. Sarah Hickey: It's important because we need to know what the concentration is, because the dose is individualized for each patient. Their assumption was, we were using the entire bag, so the full four grams would be given to one patient, which isn't the case. We use it as a stock solution and we take an individual dose out of that bag for each patient.

M^{me} France Gélinas: Were you surprised when you heard that?

Ms. Sarah Hickey: I was concerned, I guess.

M^{me} France Gélinas: Sorry. I didn't hear you.

Ms. Sarah Hickey: Surprised, I guess. I was just trying to think through the situation. I wasn't interjecting emotion into it.

M^{me} France Gélinas: Okay. I think I follow your train of thought. So here you are on the phone being told by a pharmacist that a pharmacist thinks that a patient would get four grams of that chemo drug. That would have been common knowledge—not to me, but to pharmacists—that this is not a single dose.

Ms. Sarah Hickey: I wasn't sure if that individual that we were speaking to was a technician or a pharmacist. But if a pharmacist had experience in oncology, then they would know that that dose would be too high.

M^{me} France Gélinas: Then you go on to say you made a clinical decision for that one patient, taking into account who they were and everything else. In your clinical decision, you say, "And we knew it was not a stronger concentration of medication...." Why was this a relevant factor in your decision-making?

Ms. Sarah Hickey: It was just part of my thought process, what I knew about the product. It may have been more clinically significant had it been in a higher concentration.

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M^{me} France Gélinas: How so?

Ms. Sarah Hickey: You're potentially giving more drug and increasing the risk of side effects. Again, had it been an overconcentration, I would have had to think about the whole clinical situation, depending on how significant the difference was.

M^{me} France Gélinas: I take it that you know the patient who was there that day. You know the thought process and the decision process that you used to make the decisions to say, "Go ahead and use it." I'm sure you've had many nights to think over that decision. Are you still comfortable with it?

Ms. Sarah Hickey: Yes, I still am comfortable with that decision.

M^{me} France Gélinas: Okay. Then you go on to say that later that afternoon, we received a call from Lakeridge that advised us not to use the Marchese product. Who was it who called you?

Ms. Sarah Hickey: It was the same pharmacist who I had spoken to earlier in the afternoon.

M^{me} France Gélinas: Okay. Did they give any details as to why that was so, what you were to do with it—anything else?

Ms. Sarah Hickey: No.

M^{me} France Gélinas: How long was that conversation?

Ms. Sarah Hickey: A few moments.

M^{me} France Gélinas: Did they call you directly?

Ms. Sarah Hickey: Yes.

M^{me} France Gélinas: Anybody else?

Ms. Sarah Hickey: I don't know.

M^{me} France Gélinas: So you took the call and what did they say?

Ms. Sarah Hickey: They just said, "Do not use the Marchese cyclophosphamide or gemcitabine products."

M^{me} France Gélinas: I'm guessing you knew that you had patients who would have needed that drug the next day or the day after. What goes through your mind when all of a sudden, a needed drug is shelved like that?

Ms. Sarah Hickey: I left that work up to our pharmacy assistants, who are primarily responsible for procuring the drugs they need for the clinic the next day.

M^{me} France Gélinas: So once you received that information, what did you do with it? Who did you call? Who did you talk to?

Ms. Sarah Hickey: Oh yes, I did—I sent an email to the pharmacy assistants. They had already gone for the day at this point.

M^{me} France Gélinas: Did you hear back after work the next day or something?

Ms. Sarah Hickey: Yes, I think we spoke about it the next day.

M^{me} France Gélinas: And when you say "we," who is that?

Ms. Sarah Hickey: Me and the other—the pharmacy assistants who were working.

M^{me} France Gélinas: That's Judy and Craig?

Ms. Sarah Hickey: Yes.

M^{me} France Gélinas: And what did they have to say?

Ms. Sarah Hickey: That they had removed the product from the clinic.

M^{me} France Gélinas: And they never mentioned as to, "It's going to take us longer to prepare this," or—

Ms. Sarah Hickey: No, they didn't.

M^{me} France Gélinas: Did you know that they were to start preparing it in-house?

Ms. Sarah Hickey: Yes. They would have to use vials to prepare, and I knew that, yes.

M^{me} France Gélinas: And did you feel they were ready, equipped and knowledgeable to do that?

Ms. Sarah Hickey: Oh, yes.

M^{me} France Gélinas: What made you so sure?

Ms. Sarah Hickey: Well, I work with these assistants every day and they're very competent at their job.

M^{me} France Gélinas: And you knew that you had the drug in-house to dilute it yourself?

Ms. Sarah Hickey: I didn't ask them and they didn't express any concerns about that.

M^{me} France Gélinas: The next time you had to check that the right drug, the right dosage was being given to the right patient, did you follow up at all to see where it was coming from, how it had happened to be there for you to check?

Ms. Sarah Hickey: I don't actually physically check the product. The product is prepared in the chemo pharmacy and the pharmacy assistants check one another's preparations.

M^{me} France Gélinas: Does your hospital use a lot of admixed drugs in chemotherapy?

Ms. Sarah Hickey: I don't know if they use a lot of them, no. I don't know that.

M^{me} France Gélinas: Do they use any other ones except for the two that we're dealing with today?

Ms. Sarah Hickey: Do you mean buy products that come partially prepared, or prepared from a manufacturer, that they don't—for example, there are some other products that they use that come premixed. There would be a fluorouracil infuser bottle or a pamidronate infusion that comes in an ambulatory infusion device. In that case, they would check to make sure it's the right drug, and they would put a label on it and not have to mix it. Is that what you are asking?

M^{me} France Gélinas: Yes.

I'll let it go around.

The Chair (Mr. Ernie Hardeman): Okay, thank you very much. We'll then go to Ms. Jaczek.

Ms. Helena Jaczek: Yes, thank you. Thank you for your presentation, Ms. Hickey. First of all, on behalf of the government, I'd like to congratulate you and your team, Craig and Judy, for acting so expeditiously and doing the follow-up with Marchese and, obviously, doing the very best you could in trying to get to the bottom of the difference in the new product that was received.

You came to the conclusion that the difference between the 37.4 milligrams per millilitre that you had calculated, based on the Hospira bag, compared to the 38 milligrams per millilitre, was probably not clinically significant. I think most people could—as a physician, I can see that that was a very small difference, and I would respect your professional opinion. I'm just wondering: Did you check with the oncologist? Did you go to anybody else to talk about the discrepancy and to sort of have a conversation about this?

Ms. Sarah Hickey: In this situation, because the difference was very small, I felt it was within my scope of practice to continue using the product for that patient.

Ms. Helena Jaczek: Fair enough. Actually, I'd like to talk a little bit about the college oversight of pharmacists, sort of in general. Obviously, you've told us that you're a registered pharmacist with the Ontario College of Pharmacists and in good standing, and a member of the Canadian Association of Pharmacy in Oncology. What type of oversight does the College of Pharmacists have over you? You're working in a hospital setting. Just describe what maintaining your certification means.

Ms. Sarah Hickey: To be a member of the Ontario College of Pharmacists, I have to maintain a learning

portfolio, where I've demonstrated that I've maintained my knowledge. I have to work a certain amount of hours within a certain time frame to maintain my competency. Then I'm—

Ms. Helena Jaczek: And you report this on an annual basis?

Ms. Sarah Hickey: Yes. Annually, we declare if we've worked the appropriate hours. The learning portfolio is an audit process, so within five years, every member is asked to provide their learning portfolio to the college, in a randomly selected time frame.

Ms. Helena Jaczek: What would be the difference if you were working at an independent pharmacy, a community pharmacy? How would that differ, that oversight?

Ms. Sarah Hickey: As far as individual pharmacists—we are all expected to conform to the laws and regulations. But in hospital pharmacy practice, the pharmacy itself is not accredited by the Ontario College of Pharmacists, whereas a drugstore or a community pharmacy is.

Ms. Helena Jaczek: Do you have any opinion as to whether that should change? We've heard that in some jurisdictions, there is the ability of the College of Pharmacists—I believe it was in BC—to come into a hospital and actually do some on-site inspection.

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Ms. Sarah Hickey: No, I don't really have an opinion on that. Sorry.

Ms. Helena Jaczek: But you wouldn't have any objection?

Ms. Sarah Hickey: No.

Ms. Helena Jaczek: Okay. There have been some changes to regulations the College of Pharmacists has brought in here to respond to the concerns related to off-site drug compounding. Are you aware of that?

Ms. Sarah Hickey: Yes.

Ms. Helena Jaczek: Do you feel that that's appropriate? Does that give you some measure of comfort in the fact that you might be receiving compounded drugs from another source?

Ms. Sarah Hickey: I feel that if that's what the experts involved in the process have decided is best so that an outsourced product that has a problem with it isn't discovered by front-line workers moments before administering the drug—if that's part of a solution—then yes, I'm in favour of that.

Ms. Helena Jaczek: In terms of other compounded drugs—of course, we know about cyclophosphamide and gemcitabine, but what other compounded drugs does the Peterborough site of Lakeridge receive?

Ms. Sarah Hickey: I know that they have received fluorouracil, which is another chemotherapy agent, in a premixed infuser bottle. So an ambulatory infusion pump that's pre-made to various common doses is something that we've used, as well as another drug called pamidronate that also comes in an ambulatory infusion.

Ms. Helena Jaczek: And are you confident about the use of those prepared products that arrive in your pharmacy?

Ms. Sarah Hickey: Yes.

Ms. Helena Jaczek: And that's because you've had the experience of using them over time?

Ms. Sarah Hickey: Since I began working in oncology they've been used, so yes.

Ms. Helena Jaczek: And the concentration or the dose is very clear?

Ms. Sarah Hickey: I've never had any concerns about them, no.

Ms. Helena Jaczek: Okay. I think that's all for now, Mr. Chair.

The Chair (Mr. Ernie Hardeman): Okay, thank you very much. The official opposition, Ms. McKenna.

Mrs. Jane McKenna: I just have one question for you. Usually after something has happened you can sit back and look and think, "Gee, what would I have done differently?" Is there anything you would have done differently now that it's passed and you can sit back and digest everything that's gone on?

Ms. Sarah Hickey: I feel strongly that we made the right decision for the patient at that moment. It wasn't ideal, the situation, but we are asked to make difficult decisions at times for patient care, and in that case it was the best decision for the patient.

Mrs. Jane McKenna: Okay. Anybody else that was around you—do you feel that anybody let you down for having to make that decision solely by yourself? Do you feel anybody else could have done anything to have taken some of that weight off of your shoulders?

Ms. Sarah Hickey: No, I think we all do our very best.

Mrs. Jane McKenna: And the communication was very fluent through the whole process that was going on. Considering it was something that you had never dealt with before, did you feel that the open lines of communication were just that?

Ms. Sarah Hickey: Yes.

Mrs. Jane McKenna: Okay. That's it for me.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Gélinas.

M^{me} France Gélinas: How long would you say you have been working with cyclophosphamide?

Ms. Sarah Hickey: I've had some experience with it previous to working full-time in oncology, but most of my experience has been in the last four years.

M^{me} France Gélinas: And did you know what the stability data was for that drug?

Ms. Sarah Hickey: Cyclophosphamide in particular?

M^{me} France Gélinas: Cyclophosphamide, yes.

Ms. Sarah Hickey: I know where to find the information about stability.

M^{me} France Gélinas: Okay. When you were getting it from Baxter it was not through a cold chain; it was room temperature. One of the things that alerted, I want to call him Greg—I forgot his name—was that he now got it out of the fridge. Did the fact that it was not refrigerated and the stability data was rather short for room temperature—I'm curious to see how this drug was delivered to you and used within such a short time frame.

Ms. Sarah Hickey: I just want to clarify: Are you referring to gemcitabine or cyclophosphamide?

M^{me} France Gélinas: Cyclophosphamide.

Ms. Sarah Hickey: I had no conversations about cyclophosphamide with the pharmacy assistants about any concerns at storage.

M^{me} France Gélinas: He told us that one of the things that alerted him that he was dealing with a different product was that when he got it from Baxter he got it from the fridge, and before it never used to be in the fridge.

Ms. Sarah Hickey: That wasn't a concern he discussed with me.

M^{me} France Gélinas: So you don't know how long your hospital would have had this product before?

Ms. Sarah Hickey: No.

M^{me} France Gélinas: You don't know when the drug comes in and when it gets used?

Ms. Sarah Hickey: No, I don't.

M^{me} France Gélinas: How do you ensure that you're using the products within the allotted stability time?

Ms. Sarah Hickey: That would be the role of the pharmacy assistants.

M^{me} France Gélinas: This is not something that a pharmacist would ever advise on?

Ms. Sarah Hickey: If they had concerns with stability information, I would gladly help them, but I'm quite removed from the pharmacy itself and work with a team of physicians and nurses.

M^{me} France Gélinas: Right now, are you handling those drugs any different than before March 20?

Ms. Sarah Hickey: I don't physically handle any of the drugs. I just review the orders.

M^{me} France Gélinas: Do you know if the staff complement in oncology pharmacy has changed at your hospital since March 20?

Ms. Sarah Hickey: No, it hasn't.

M^{me} France Gélinas: Has the work that you do changed at all?

Ms. Sarah Hickey: No, it hasn't.

M^{me} France Gélinas: The government has new regulations coming out where hospitals will be responsible to find out if the drugs they're purchasing are coming from an accredited source. Who do you think will be responsible for that check?

Ms. Sarah Hickey: I'm not sure.

M^{me} France Gélinas: Do you figure it would come to a pharmacist?

Ms. Sarah Hickey: I suppose it would be different in every hospital, but I'm not really sure.

M^{me} France Gélinas: Do you figure this is information that a pharmacist would have?

Ms. Sarah Hickey: Information of where the product was purchased, whether from—

M^{me} France Gélinas: An accredited source or not.

Ms. Sarah Hickey: It could be important, but from my perspective, where I do my work, it wouldn't be a question that I would ask while I'm reviewing the orders.

M^{me} France Gélinas: Dr. Thiessen was there just before you. Had you met him before?

Ms. Sarah Hickey: Yes.

M^{me} France Gélinas: In what circumstances?

Ms. Sarah Hickey: When he came to our hospital, we had a meeting.

M^{me} France Gélinas: When was that?

Ms. Sarah Hickey: I don't know the exact date, but it was concerning the events of March 20.

M^{me} France Gélinas: Have you had more than one meeting with Dr. Thiessen?

Ms. Sarah Hickey: Just one.

M^{me} France Gélinas: Who else was present when you were there?

Ms. Sarah Hickey: My director was there. The manager of the cancer clinic, the pharmacy assistants—

M^{me} France Gélinas: How many pharmacy assistants were there?

Ms. Sarah Hickey: There were three.

M^{me} France Gélinas: Aside from the two that we've talked to, who's the third one?

Ms. Sarah Hickey: Can I give her name to the Clerk?

M^{me} France Gélinas: Why do we have to go through this again, remind me?

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Ms. Sarah Hickey: I didn't have a chance to speak to her—because she was away on vacation—that I would mention her name here today, so if it would be okay with you, I'd like to leave it with the Clerk instead.

M^{me} France Gélinas: Okay. And the third assistant took a place in the meeting?

Ms. Sarah Hickey: Yes.

M^{me} France Gélinas: Why was she invited?

Ms. Sarah Hickey: Because she was working in the clinic on that day.

M^{me} France Gélinas: And who else?

Ms. Sarah Hickey: Judy Turner and Craig Woudsma.

M^{me} France Gélinas: Who else was at the meeting?

Ms. Sarah Hickey: Oh, at the meeting?

M^{me} France Gélinas: You said your director, manager of cancer—the three technicians, yourself—

Ms. Sarah Hickey: Yes, and Kate Crawford, our lawyer. That's all I can remember who was there that day.

M^{me} France Gélinas: Do you remember how long the meeting lasted?

Ms. Sarah Hickey: It was about an hour.

M^{me} France Gélinas: About an hour. Did you have a chance to talk during that meeting?

Ms. Sarah Hickey: Yes, I did.

M^{me} France Gélinas: What were some of the questions that were directed at you?

Ms. Sarah Hickey: Dr. Thiessen just asked for us to explain in our own words our involvement, and he asked—I don't remember the specific questions, but just questions to help direct our thoughts.

M^{me} France Gélinas: Do you remember what you said?

Ms. Sarah Hickey: Yes. I said the same things that were in my opening statement.

M^{me} France Gélinas: When was that opening statement prepared for you?

Ms. Sarah Hickey: I prepared it myself, but I did have help with it from someone in our communications department. It was on Friday and over the weekend I worked on it.

M^{me} France Gélinas: Did you prepare any notes for when you met with Dr. Thiessen?

Ms. Sarah Hickey: No.

M^{me} France Gélinas: Did anybody else?

Ms. Sarah Hickey: I'm not sure.

M^{me} France Gélinas: Not that you could see?

Ms. Sarah Hickey: No.

The Chair (Mr. Ernie Hardeman): We're just about to finish, so if you have one more question, you can go ahead.

M^{me} France Gélinas: The question of concentration is something that Dr. Thiessen has raised with us, the nominal content versus the accuracy in content and the precision in content. To you, are those concepts basic to a pharmacist, or is this something that is novel to you?

Ms. Sarah Hickey: No. That's common knowledge.

M^{me} France Gélinas: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation.

The government side: Ms. Jaczek.

Ms. Helena Jaczek: I just want to understand the relationship between the Peterborough site and Lakeridge. When the pharmacist phoned you from Lakeridge to say, "Don't use the product anymore; quarantine the Marchese product," is that pharmacist sort of the senior

pharmacist? I mean, do you report to that pharmacist at all? How does this hierarchy work between the two sites?

Ms. Sarah Hickey: No, they weren't my supervisor. We work collaboratively. I don't—

Ms. Helena Jaczek: When you got the phone call, did you question why this decision was being made? Because you had decided, at least for the individual patient, that it wasn't going to make much difference. So what was that conversation about?

Ms. Sarah Hickey: At the time, no, I didn't question their decision.

Ms. Helena Jaczek: I see. So she just said it's quarantined, and that was it. Was there conversation within your unit in Peterborough about the situation, then, subsequent to that phone call?

Ms. Sarah Hickey: Just that communication about the directive from Lakeridge, what we were to do with the product.

Ms. Helena Jaczek: Okay. Thank you. That's all.

The Chair (Mr. Ernie Hardeman): Thank you very much. Are there any further questions from—

Mrs. Jane McKenna: Yes.

The Chair (Mr. Ernie Hardeman): Oh, you've used all your time. I shouldn't say "from anyone," then, should I?

That does conclude the presentation this afternoon. We want to thank you very much for coming in.

Ms. Sarah Hickey: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. Now, with the committee's indulgence, if we could have a few minutes in an in-camera session, we have an issue we need to discuss for evidence.

The committee continued in closed session at 1616.

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Standing Committee on Social Policy

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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 3 June 2013

Lundi 3 juin 2013

*The committee met at 1420 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIES

The Chair (Mr. Ernie Hardeman): I call to order the June 3 committee on social policy, a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

MS. NANCY FROUDE

The Chair (Mr. Ernie Hardeman): The first delegation we have today is Lakeridge Health centre: Nancy Froude. If Nancy would take a seat at the front of the table.

There are a number of items on the committee's desks that we will be discussing after we have our delegations today. We haven't forgotten about those.

With that, we want to thank you for coming in today, Nancy. We do want to point out, obviously, that we're doing this committee hearing under oath. So the Clerk will deal with that. Either you will affirm or swear the oath before we start the presentation. Mr. Clerk?

The Clerk of the Committee (Mr. William Short): Would you prefer an oath or an affirmation?

Ms. Nancy Froude: An oath, please.

The Clerk of the Committee (Mr. William Short): The Bible is in front of you, there.

Ms. Froude, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Nancy Froude: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we will start the presentation. We have 20 minutes for you to make your presentation. You can use any or all of that. Then when you've completed the presentation, we will have questions for 20 minutes from each caucus. This time, the rotation will begin with the official opposition.

Thank you very much again for coming in. The floor is yours.

Ms. Nancy Froude: Thank you. Good afternoon, everybody. My name is Nancy Froude, and I would like

to thank you for inviting me to address the Standing Committee on Social Policy today.

I'd like to begin by telling you a little bit about myself, my qualifications and experience, and then I will address the events that occurred on March 20.

I am a member of the Ontario College of Pharmacists, in good standing, and graduated from the University of Toronto with a bachelor of science degree in pharmacy in 1992. Upon graduation, I began my practice in various community pharmacy settings, experiencing settings that varied from a small, independent pharmacy to a big chain drugstore.

In 2006, I began a temporary position at Lakeridge Health in the pharmacy department to cover a maternity leave. I took the position because I wanted to gain the experience of working in a more clinical hospital setting. Following that contract, I returned to work in a community pharmacy in the Port Perry area. I was subsequently contacted by Lakeridge Health as they were recruiting for their pharmacy team in the R.S. McLaughlin Durham Regional Cancer Centre. I was hired in 2008 by Lakeridge Health to join the pharmacy team within the cancer centre, where I have worked ever since.

My main role there relates to the retail pharmacy within the cancer centre. It is a dispensing pharmacy for our outpatients within the cancer centre so our patients can access medications for oral chemotherapy to be taken at home, anti-nausea medications and other injectable medications related to their care that may not be available in a typical community pharmacy. This also provides a chance for a pharmacist to review prescriptions for oral chemotherapy and to provide thorough counselling to our patients.

My other duties in the cancer centre include reviewing chemotherapy treatment orders, blood work, checking of doses and monitoring for drug interactions.

I am part of the multidisciplinary team and work closely with the nurses, physicians, dietitians and, on occasion, social workers. I am also part of the oncology clinical trials team and work closely with other members of that team. We comprise one of the largest community oncology trials teams in the country.

Most recently, I was asked to take on an additional role as the Central East region lead for the smoking cessation program. The role as regional lead will provide me with the opportunity to work with Cancer Care On-

tario and leads from other cancer centres in the province to help improve the lives of cancer patients and their families.

On March 20, I received a call in the afternoon from Sarah Hickey. Sarah is a pharmacist and colleague of mine who works out of the cancer clinic at Peterborough Regional Health Centre. On occasion, Sarah will call in to the cancer centre pharmacy in Oshawa, particularly regarding computer issues, to consult or to seek a second opinion.

That day, Sarah told me a pharmacy assistant in Peterborough had noticed a difference in the labelling on the medication bags for gemcitabine that we had recently begun receiving from a company called Marchese—a change from our previous supplier, Baxter. Sarah told me the concern was over the concentration labelling on the bag. The Marchese product was labelled as four grams in 100 millilitres, whereas the previous bags were labelled as four grams in 104 millilitres. I looked up the drug entry for gemcitabine in our computer to verify the concentration that our computer system was working off of, and realized that something was not right. Since I was unsure of the scope of the problem, I told Sarah that I needed to investigate the discrepancy further and that I would call her back.

I then immediately went into what is called our “clean room,” which is the area where the chemotherapy drugs are prepared, to speak to our pharmacy assistants who handle the drugs directly. I asked to see the product, and the first thing I thought was, “This just doesn’t seem right.” The company was using a Hospira 100-millilitre pre-filled IV solution bag and there would be overfill, so I wondered how the supplier was using these bags to make the gemcitabine. I was told by the assistants that our previous supplier had been using empty Viaflex bags in their production process.

We then decided as a group that the only way to be certain about the volume within the bag was to pull it all out and measure using syringes. One of the pharmacy assistants then went into what is called “the hood,” or the biohazard safety cabinet, and withdrew the entire volume out of a bag of gemcitabine into syringes to be able to verify the actual volume within the bag. She called me back into the clean room when she was finished and we looked and saw that it was actually 111 millilitres, not the 100 millilitres as labelled on the bag. This led us to believe the likely issue was that the supplier did not pull the overfill out of the bag as part of their processes.

Our next thought was, “What else are we getting from them?” The pharmacy assistant then advised me that we were also receiving cyclophosphamide from the same manufacturer. When we looked at that medication, we saw it was in a 250-millilitre pre-filled IV solution bag, which to me seemed even more wrong. We went through the same process of pulling the volume out of the bag, and it was clear they had again not accounted for the overfill in their production process. In what was labelled to be a 200-millilitre volume, there were actually 223 millilitres. We came to the conclusion that the difference here was more significant.

The results of these two tests made it clear to us that we needed to call the manager of the pharmacy immediately to let her know. While one of the pharmacy assistants started the process of calling and then paging the manager, I phoned Sarah Hickey back at the cancer clinic in Peterborough. I had a very brief discussion with Sarah and advised her that they should not use the product from Marchese any further.

By then, the manager of our pharmacy had come to the cancer centre pharmacy and we went over our conversations and the volumes we had found in the bags. The decision was made that we were not going to use the product the next day and to use the vials as supplied directly from the manufacturer.

This is where my involvement ended.

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I would like to put on the record how proud I am of the pharmacy teams at Lakeridge Health and the Peterborough regional cancer centre. We definitely have to keep asking questions because no matter how many computerized systems are in place or how many checks and double-checks are involved, we’re all just human, and we are all subject to the frailties of human error, miscommunication and misunderstanding. But we all got into health care and into the profession of pharmacy because we want to use our skills to help people feel better and live healthier lives by having the safest pharmacy with the highest possible standards.

After working a summer job during high school at a small family-run community pharmacy, I was immediately drawn to the profession. One particular pharmacist there made a real difference in people’s well-being, and that has stuck with me. I enjoy the daily interaction with patients, and have developed relationships with them and their families as they come in to pick up their prescriptions and ask for medication-related information.

I have high expectations and standards set for myself, and when I have prescriptions filled for my kids and family, I expect my colleagues to have done the same, and that is what our entire team at Lakeridge Health brings to our pharmacy.

I’d like to thank you for the opportunity to address you all today, and I look forward to answering your questions to the best of my abilities.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. As I said previously, we’ll start with the official opposition, Mr. Yurek.

Mr. Jeff Yurek: Thank you, Chair. Thank you, Ms. Froude, for coming in and spending your day with us—or afternoon. Just a few questions that have come up: In your comments, you mentioned that Baxter’s bags were 104 millilitres before, not 100 millilitres.

Ms. Nancy Froude: Correct.

Mr. Jeff Yurek: That’s interesting. Did you have any knowledge of the contract with Medbuy at all?

Ms. Nancy Froude: I did not.

Mr. Jeff Yurek: And you worked in the retail part of the hospital pharmacy?

Ms. Nancy Froude: Right. So we have an outpatient pharmacy within our cancer centre, so that patients can get medications filled there to take home with them.

Mr. Jeff Yurek: And that's separate from the hospital pharmacy?

Ms. Nancy Froude: Correct. Well, it's within the cancer centre pharmacy, so we're in the same location geographically.

Mr. Jeff Yurek: Because your section, being the retail, would be inspected by OCP?

Ms. Nancy Froude: We're not a fully accredited pharmacy, so no, we are not.

Mr. Jeff Yurek: Okay. How much time had elapsed between you getting the first call from Sarah and then going and figuring out what went wrong and then calling Sarah back? How quick?

Ms. Nancy Froude: It was probably a little over an hour. I'm not sure of the exact times. There was a lot going on at the time, but somewhere around that time frame.

Mr. Jeff Yurek: But it was a fairly quick response?

Ms. Nancy Froude: Yes.

Mr. Jeff Yurek: My other question is—then I'm going to pass it on to the third party and then I'll carry on later—with regard to the product supplied from Medbuy, if there's a problem with a product, is there some sort of procedure in place to which you could send the complaint to Medbuy to give them your cautions or warnings of why you're not happy with the product?

Ms. Nancy Froude: I'm not aware of any formal process that's in place.

Mr. Jeff Yurek: Where would you report that to? To your manager—

Ms. Nancy Froude: I would, yes. I think it would depend on the issue that needed to be questioned as well a little bit.

Mr. Jeff Yurek: Okay. But you don't know of any process at all of—

Ms. Nancy Froude: I'm not aware of any formal process.

Mr. Jeff Yurek: Now, if you have a product from GlaxoSmithKline that is defective, do you have a process to deal with that product?

Ms. Nancy Froude: We do have a pharmacy assistant who deals with inventory and ordering, and she can sometimes be a resource or, again, depending on what the issue is, I may take it upon myself to call GlaxoSmithKline as a pharmacist and speak to somebody in their medical department.

Mr. Jeff Yurek: Okay, but you don't have anything for Medbuy?

Ms. Nancy Froude: Correct.

Mr. Jeff Yurek: Okay. I'll hold until later and pass it on.

The Chair (Mr. Ernie Hardeman): Okay, very good. Ms. Gélinas.

M^{me} France Gélinas: Thank you for coming, Ms. Froude. The first question I'd like to ask is from your statement. You say you get the phone call from Sarah.

You immediately go and talk to a pharmacy technician dealing with those drugs, and then you go back to the computer. You say, "I looked up the drug entry for gemcitabine in our computer to verify the concentration that the computer system was working off of, and realized something was not right." What exactly are you looking at when you make this statement?

Ms. Nancy Froude: Basically, I looked at the computer first to see what we had entered as the concentration for gemcitabine.

M^{me} France Gélinas: What had you entered?

Ms. Nancy Froude: It was entered as 38 milligrams.

M^{me} France Gélinas: Where do you figure that entry came from?

Ms. Nancy Froude: That entry is entered, again, by pharmacy staff.

M^{me} France Gélinas: Where would they have gotten this number, the 38?

Ms. Nancy Froude: Based on the product monograph.

M^{me} France Gélinas: From Baxter or from Marchese or both?

Ms. Nancy Froude: The 38 would have come from Baxter.

M^{me} France Gélinas: And that same information from the monograph was carried forward although you had changed suppliers.

Ms. Nancy Froude: Correct.

M^{me} France Gélinas: I don't want to put words in your mouth. You realized something was not right because some of the information for the monograph came from one supplier while you were looking at a different supplier?

Ms. Nancy Froude: No, I made that conclusion because when I looked in the computer, it said 38 milligrams per millilitre. Going by what they had on the bag, the four grams in 100 would make it 40 milligrams per millilitre. So I knew that something wasn't matching.

M^{me} France Gélinas: What you had in the computer should have matched what was on the bag. How come it didn't?

Ms. Nancy Froude: I don't know the answer to that.

M^{me} France Gélinas: Have you gone back since then to see where the disconnect happened?

Ms. Nancy Froude: I have not.

M^{me} France Gélinas: Why not?

Ms. Nancy Froude: That's why I involved our pharmacy manager: to deal with those concerns.

M^{me} France Gélinas: Are you confident that everything else that comes from the monograph that is in your computer is accurate, or could that kind of disconnect happen with other drugs?

Ms. Nancy Froude: I'm confident that what is entered in our computer system is accurate.

M^{me} France Gélinas: And you're confident because—

Ms. Nancy Froude: Because of the staff that we have working. Things are checked and double-checked.

M^{me} France Gélinas: Things were checked and double-checked for that one also. But then you knew that something was wrong.

Ms. Nancy Froude: Correct.

M^{me} France Gélinas: What am I missing here?

Ms. Nancy Froude: I'm not sure.

M^{me} France Gélinas: All right. You go on to say, "I then immediately went into what is called our 'clean room'—the area where chemotherapy drugs are prepared—to speak to our pharmacy assistants...." Which one was it that you spoke to?

Ms. Nancy Froude: I spoke with Jodi Stamp.

M^{me} France Gélinas: She's the one who went under the hood and retrieved the liquid from the bag?

Ms. Nancy Froude: Yes, she is.

M^{me} France Gélinas: She's also the one who remembered that the products from Baxter came from Viaflex bags.

Ms. Nancy Froude: Yes.

M^{me} France Gélinas: You went on to check for the other cancer drug, the cyclophosphamide, then did your other little experiment, and found out. You called the manager of the pharmacy. Remind me who the manager is again.

Ms. Nancy Froude: Her name is Linda Skinner.

M^{me} France Gélinas: What was your conversation like with Linda?

Ms. Nancy Froude: You can imagine how everybody was feeling at that point. We had a lot of information to get across to Linda. We reviewed the information that we had retrieved from doing our sampling volume from the bags so she was aware of what processes we had taken and what the results of that process were, and explained to her the issues that would have, what approximately the percentage difference may be on the dosing, and just basically informed her of what we had discovered.

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M^{me} France Gélinas: What did she say? How did she react?

Ms. Nancy Froude: Like the rest of us, I think, shock and disbelief and sort of not sure how big the problem was at that point.

M^{me} France Gélinas: Were all three of you, Linda, yourself—who made the decision to say, "Let's not touch this anymore. Let's mix our own"?

Ms. Nancy Froude: Linda Skinner did.

M^{me} France Gélinas: And you supported that?

Ms. Nancy Froude: Absolutely.

M^{me} France Gélinas: You knew it was the right decision to make.

Ms. Nancy Froude: It was really the only decision to make at the time. There was no way we could continue to use a product that wasn't right.

M^{me} France Gélinas: So the next day, you said, "The decision was made that we were not going to use that product the next day and use the vials as supplied directly by the manufacturer." If you were getting them premixed, why did you still have them in vial form in your hospital?

Ms. Nancy Froude: We always have a backup supply.

M^{me} France Gélinas: And that was part of your backup?

Ms. Nancy Froude: Yes.

M^{me} France Gélinas: Had you been using backups while you were with Baxter? Do you use them when you run out?

Ms. Nancy Froude: They would be on hand in case we needed them if we had issues with supply from Baxter. I don't know whether or how often we needed to use them, but I know that we did have a small supply on hand.

M^{me} France Gélinas: And you had enough for the next day?

Ms. Nancy Froude: Yes, and then arrangements were made to order more.

M^{me} France Gélinas: And who do you get your vials from?

Ms. Nancy Froude: I'm not sure currently what brand we're using. I don't work directly with the products. I can't answer that question.

M^{me} France Gélinas: How much of it would you say you use in a typical week or typical day?

Ms. Nancy Froude: Both of those drugs are quite frequently used oncology products, so we would use them regularly through the day. They're used for various types of treatments for cancer patients.

M^{me} France Gélinas: When we talk specifically about cyclophosphamide, was there any doubt in your mind that 250 millilitres could ever be used on a single patient?

Ms. Nancy Froude: With a knowledge of oncology, no. It just wouldn't seem reasonable to use that type of a dose.

M^{me} France Gélinas: How well known, would you say, would that be to most pharmacists?

Ms. Nancy Froude: Oncology is a very specialized field, but really, if any pharmacist is working with a product they're not familiar with, they need to make themselves familiar with it.

M^{me} France Gélinas: So a pharmacist who had been working with cyclophosphamide, you would expect that pharmacist to know how it's being used to treat patients and which concentration.

Ms. Nancy Froude: Definitely, yes.

M^{me} France Gélinas: And you knew that this was a medication that has to be concentration-specific?

Ms. Nancy Froude: Yes.

M^{me} France Gélinas: What do you know about—and the word just escapes me—how long this thing is good for? It's called—

Mr. Jeff Yurek: Stability?

M^{me} France Gélinas: Stability, thank you. What do you know about the stability? We'll take them one at a time. We'll start with cyclo. What do you know about the stability of this drug, cyclophosphamide?

Ms. Nancy Froude: Again, I don't handle the drugs necessarily directly, but we do definitely have references

available within the pharmacy to find that information. If you want that, I could leave it with the Clerk.

M^{me} France Gélinas: Sure, but I'm also interested as to where you would go. You're a working oncology pharmacist right now in a hospital, in a cancer centre in Ontario. Where would you go to find that information at work?

Ms. Nancy Froude: There are various online sources that are available to find that information. Probably the most common one I would reference or go to is the British Columbia Cancer Agency website. There are multiple references available.

M^{me} France Gélinas: What happens if the manufacturers have done their own? How would you find that out?

Ms. Nancy Froude: A lot of manufacturers, if they've done in-house studies, will not always release their information, so it is difficult information to access.

M^{me} France Gélinas: Okay, so I'll tell you what I'm trying to do and you tell me how it works in the real world.

Ms. Nancy Froude: Okay.

M^{me} France Gélinas: We are told that one of the cancer agents is stable for four days at room temperature. We know, through the supply chain, that your cancer centre is getting this at room temperature. What we don't know, or what I don't know: I don't see any dates on the information that was shared with us. How do you know when the date is up? Where is this information carried through to you?

Ms. Nancy Froude: I'm not sure I understand your question, so if I don't answer you properly, please let me know.

Drugs would come with that expiry date on them, if we've gotten them from a manufacturer. As part of the labelling, there's an expiry date. Sorry, does that answer your question?

M^{me} France Gélinas: Yes, that's exactly what I'm looking for, except that on the labelling that we get for cyclophosphamide—we have found out that at room temperature, its expiry date is basically four days from manufacturing, but on the labelling that is available to you, that you have shared with this committee, there are no dates. So I'm guessing it's probably in a computer—I have no idea. I won't guess.

So if it's not on the labelling that was photocopied to us—we have a photocopy of the labelling on the bag. We see the names of the drugs, we see the number of grams, we see the 250 millilitres, but we don't see a date.

Ms. Nancy Froude: There should be an expiry date on the label.

M^{me} France Gélinas: There should be expiry dates on the labels. Okay. All right. So the one date that we see on the label would be the expiry?

Ms. Nancy Froude: It depends what reference is made in regard to that date. Some might have a produced on date. Others may have an expiry date.

M^{me} France Gélinas: Okay, but it should be on the label, no matter what. That information is information you expect to be available on the label.

Ms. Nancy Froude: Correct.

M^{me} France Gélinas: Is it also available someplace else?

Ms. Nancy Froude: I guess if I had to question it, I could call and ask for the—because they'd have to have a record of a lot number. I guess there's a way to trace it back, but I've never had to deal with that, so I'm not—

M^{me} France Gélinas: But the way that information is carried from the manufacturer to you is, basically, right on the label you will see the expiry date.

Ms. Nancy Froude: Correct.

M^{me} France Gélinas: Okay. This is where you expect to see it, and this is where it would be most useful.

Ms. Nancy Froude: That's the first place I would look, yes.

M^{me} France Gélinas: Okay. I'm going to let it go around.

The Chair (Mr. Ernie Hardeman): Okay, thank you very much. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Ms. Froude, for coming in. Again, I think we all feel that it was Peterborough and Lakeridge first to detect this problem, and we congratulate you and your colleagues for being part of that discovery.

Just a few questions. When you did discover that the volume with the gemcitabine apparently inside was 111 millilitres, did it ever occur to you to simply work out what the concentration was, based on 111? I know you've referenced the electronic worksheet, but in theory, you could maybe have done that and come out with a concentration less than 38.

Ms. Nancy Froude: Exactly.

Ms. Helena Jaczek: Did you consider that option? You obviously came to a different conclusion, and you didn't follow it.

Ms. Nancy Froude: Right.

Ms. Helena Jaczek: So what was your thinking?

Ms. Nancy Froude: We were actually done making our chemotherapy treatments for the day, so we really had, at that point, no need immediately to use any more gemcitabine for the day. To be able to do what you're suggesting, which is absolutely right—you could do that process. That overfill amount in the bag is not consistent, so even though we got 111 millilitres out of that particular bag, you could take a random sample of 10 bags and they all could potentially have a different volume.

Ms. Helena Jaczek: It also occurred to me that if you couldn't be sure that the volume was correct, perhaps you might not be sure that the gemcitabine was correct. I mean, that's another possibility.

Ms. Nancy Froude: Absolutely.

Ms. Helena Jaczek: Okay. At Lakeridge, when you discovered this problem, obviously you put a moratorium on the use and you returned to using vials. I'm wondering, does the Peterborough satellite oncology clinic have those vials as well? Would they have been able to quickly make up that new solution?

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Ms. Nancy Froude: I don't work out of the Peterborough cancer centre, so I don't know the information to answer that question.

Ms. Helena Jaczek: We heard from the pharmacist on-site at Peterborough last week that she made the decision—in the best interest, as she strongly felt, of the patient—that, rather than interrupt the therapy for that patient, they went ahead and they administered that dose, which as we know was slightly under. Do you think, as a fellow pharmacist, that was a reasonable decision to make?

Ms. Nancy Froude: I think it's really hard to go back and put yourself in somebody else's shoes. You could question several different pharmacists clinically about what they would have done and you could probably get a lot of different answers to that question, and all of them could probably be backed up very soundly, so I'm not really comfortable speaking for what somebody else's decision was.

Ms. Helena Jaczek: I appreciate that. I think personally that when she made that point to us last week, I felt she was convinced herself that she had used her clinical judgment and gone ahead. As you say, there are always going to be differences of opinion.

In terms of the concept of having chemotherapeutic agents compounded off-site, could you just perhaps give us your opinion as to the advantages and disadvantages of this, ignoring the fact that there was an error in this case?

Ms. Nancy Froude: Okay. I think there are definitely advantages for us as far as the workflow within our chemo preparation area. For example, gemcitabine takes a lot of time to dissolve from its powder form into the liquid form. When we receive gemcitabine directly from the manufacturer it's a powder, so we have to dissolve it before we can put it into an IV administration bag. It takes, I think, probably several hours for it to actually dissolve in, depending on the batch and different variability. That is a very time-consuming process to be doing yourself when you have a drug that you're using in fairly high demand. I think just from a workflow and efficiency standpoint, there are definitely advantages to having things outsourced.

I think the disadvantage maybe is, you don't have control directly over the product yourself, but I think probably for us the advantages at the time definitely were more advantages than disadvantages.

Ms. Helena Jaczek: In terms of oversight, as we've heard, this admixing of compounds through Medbuy was something that obviously had been going on for some time. Were you aware of what we've come to call this grey zone, that there was no direct oversight of that process?

Ms. Nancy Froude: I wasn't really involved in any of the contracts or purchasing of the products or decisions that were made in that regard, so I don't have any input or answers to those.

Ms. Helena Jaczek: Now that we've discovered that in fact neither Health Canada nor the College of Pharmacists was doing that type of inspection, do you have any opinion on what sort of regulatory oversight might be the best?

Ms. Nancy Froude: Definitely. I feel the Ontario College of Pharmacists should be inspecting any manufacture of drug products. If you work in community pharmacy, they have very regular inspections of community pharmacies, and they're quite thorough inspections. Having been involved in that process—they'll check the references you have available, your records, how clean your shelves are, how many graduated cylinders—it's quite a detailed process and a lot of it is probably historical, but we continue to do those checks. To not have those checks everywhere where drugs are being produced or handled, to me is just not the way we should be controlling our pharmacy supply of medications.

Ms. Helena Jaczek: We've also heard that there is no particular oversight, or not to the same extent, in hospital pharmacies as there is in community retail pharmacies, rather than, of course, the pharmacists are accredited through the College of Pharmacists. Do you have an opinion as to whether it would be wise to include oversight of hospital pharmacies?

Ms. Nancy Froude: I have a very strong community pharmacy background. I was very surprised when I started working in hospitals that the college does not have any role in the pharmacies that are in hospitals, especially given the types of products that are made and handled and utilized within hospitals. For the college not to have the ability to go in and inspect them and make sure that they're meeting certain standards and guidelines—again, to me it's an unsafe process, not to have some sort of double-checks in place. I really think that the college does a good job of following up with community pharmacies.

Ms. Helena Jaczek: Have you been involved with Dr. Jake Thiessen's process at all?

Ms. Nancy Froude: Yes. Dr. Thiessen spent probably a little over an hour with myself and other members of the pharmacy team at Lakeridge Health.

Ms. Helena Jaczek: And basically, the conversation was much as you've told us about, the events of March 20?

Ms. Nancy Froude: Right. We went over exactly the events that occurred. He asked some further questions about the drugs a little bit and how they were handled, and just about our processes within the pharmacy and the production of our chemotherapy.

Ms. Helena Jaczek: Will you be looking forward to his findings? As a pharmacist, this is obviously an issue that I imagine is of considerable interest.

Ms. Nancy Froude: Yes.

Ms. Helena Jaczek: From what we've heard, Dr. Thiessen is a very well-respected member of the pharmacy community.

Ms. Nancy Froude: Definitely. Yes, he was actually one of my professors at university.

Ms. Helena Jaczek: No further questions at this point.

The Chair (Mr. Ernie Hardeman): Thank you very much. Mr. Yurek.

Mr. Jeff Yurek: I think Dr. Thiessen taught about 30 years' worth of pharmacists.

Ms. Nancy Froude: That's right.

Mr. Jeff Yurek: Just a quick few questions. Have you before at your pharmacy had any problems with any product Medbuy had procured for you? I guess one that would be admixed?

Ms. Nancy Froude: We only really have four products that we receive within chemotherapy through Medbuy sourcing out.

Mr. Jeff Yurek: What were the other two?

Ms. Nancy Froude: The other two were pamidronate and fluorouracil or 5-FU.

Mr. Jeff Yurek: When they changed over from Baxter to Marchese, was staff given a notification, "Hey, we've switched suppliers"? How was that—

Ms. Nancy Froude: Yes, there was notification that we were switching suppliers.

Mr. Jeff Yurek: Was it given out as a formal letter, memo, meeting?

Ms. Nancy Froude: There was no meeting. I believe it was just through electronic means, like emails. We have an internal system called the MOX, where messages are sent to staff. There were also some pharmacy meetings within the main pharmacy when their products were switched over, but I don't recall having one specific for the chemotherapy agents.

Mr. Jeff Yurek: Did they go over any changes they were expecting in the system? Or did they say everything would just be normal?

Ms. Nancy Froude: Right, just a notification that we were switching manufacturers.

Mr. Jeff Yurek: I just want to get back to your retail pharmacy. That's not accredited, so OCP doesn't have access to review your pharmacy. They're not part of your outpatient pharmacy.

Ms. Nancy Froude: Correct.

Mr. Jeff Yurek: You've brought up a new grey area out there: the hospital pharmacy dispensing medications to the public. Being in a community pharmacy, you would know that if the public has a problem with the medication they receive, they can either do a formal complaint with the college of pharmacy on the pharmacist, or they could do it on the pharmacy if there's a problem, so they have two avenues to seek changes in the system. Whereas with your retail pharmacy—correct me if I'm wrong—not being accredited by the OCP, they could only go through the pharmacist and not the pharmacy. They could have no recourse to lodge complaint for investigation.

Ms. Nancy Froude: That seems correct.

Mr. Jeff Yurek: Also—correct me if I'm wrong—the accredited pharmacy has to have a designated manager, which is—if you can explain what the designated manager does for the retail pharmacy.

Ms. Nancy Froude: Sure. The designated manager is the manager that's on record for that pharmacy at the college. They would have certain responsibilities above the staff pharmacists: ensuring that standards are being met, that proper reports are being run and submitted, just maintaining the standards of pharmacy.

Mr. Jeff Yurek: So not being accredited, your retail pharmacy doesn't have a designated manager?

Ms. Nancy Froude: That responsibility, I believe, would go back on to our pharmacy manager, Linda Skinner.

Mr. Jeff Yurek: And who would oversee that pharmacy? In a retail pharmacy, the OCP oversees to ensure a third party uninvolved with the company—who would do that at the hospital level?

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Ms. Nancy Froude: I guess it would go up one level, up again, to the director of—

Mr. Jeff Yurek: But that's still within the same corporate structure.

Ms. Nancy Froude: Right.

Mr. Jeff Yurek: Also, pharmacies—this might answer some stability questions. Retail pharmacies have to belong to a drug information service—

Ms. Nancy Froude: Correct, yes

Mr. Jeff Yurek:—which they can call and get all the information they want. A hospital pharmacy, unaccredited, does not. Is that correct?

Ms. Nancy Froude: Correct, although—

Mr. Jeff Yurek: They have to do their own research and stuff?

Ms. Nancy Froude: We would have access to those same databases.

Mr. Jeff Yurek: But it's not a requirement.

Ms. Nancy Froude: It's not a requirement, right.

Mr. Jeff Yurek: Do you bill the Ontario drug benefit plan?

Ms. Nancy Froude: We do. Yes, we do.

Mr. Jeff Yurek: Even though you're not accredited?

Ms. Nancy Froude: Yes. We have an account with Ontario drug benefit.

Mr. Jeff Yurek: Okay. So that would just, I think, reiterate the point I've been making. As I said earlier, you would agree with the college of pharmacy kind of expanding the scope to cover hospital pharmacies, which would take care of this grey area we've just found out about today.

Ms. Nancy Froude: Yes, right.

Mr. Jeff Yurek: Okay. Jane?

Mrs. Jane McKenna: Thank you, Nancy, for being here today. I guess my first question is—usually for myself, after something's happened and it was unexpected, I can usually sit back and then go through everything over and over again and I usually have a different outcome of what I would have done differently. Now that you've had time to think and go through the process again, would you have done anything differently?

Ms. Nancy Froude: I don't think so. I think we did a very thorough, quick check and then handed it along to the appropriate people.

Mrs. Jane McKenna: So because you have not been in a situation like this before and, sadly, there are firsts in everything or so many things, were there the proper checks and balances on who was to talk to whom and who was going to take the next level of where it would

go? Was everybody very clear on what they were supposed to be doing in the process and how it went down?

Ms. Nancy Froude: Sorry, you mean after we discovered the—

Mrs. Jane McKenna: Yes, yes.

Ms. Nancy Froude: Yes, I think so. I mean, I spoke to my pharmacy manager, who then did what she felt involved the next level up in our care system within Lakeridge Health. I think we have a very clear set of who should escalate problems to whom and when.

Mrs. Jane McKenna: Okay. Is that Linda that you're speaking about?

Ms. Nancy Froude: Right. Linda's our pharmacy manager.

Mrs. Jane McKenna: Okay. So would Linda, in the process of finding this out, which we are very grateful for, have known at the very beginning that Windsor had been using the same product for a year?

Ms. Nancy Froude: I don't know that information for sure. My impression was that she did not right that day.

Mrs. Jane McKenna: Right that day. Yes, because I'm saying, when everything's so new and then you would be wondering, because you saw it, how come another hospital had gone a year without seeing it and they're still continuing doing it, which means there haven't been any tragedies that anyone would know of or someone would have found this out by now.

Ms. Nancy Froude: Right.

Mrs. Jane McKenna: Were you concerned at all—and someone might have asked this question; I'm sorry, I came in later—when you saw the label and you, I understand, saw the label from Baxter, were you concerned? Is that what concerned you or red-flagged you right at the beginning, that the labels were different?

Ms. Nancy Froude: My biggest concern versus when I looked at the bag and that they were using a commercially available 100-millilitre bag—and I know there's overfill in that bag. It didn't seem logical to me for them to use that type of system when you don't know what the overfill is. The only way to know is to pull everything out and then just put back in what you need, which doesn't, just from an efficiency standpoint and safety standpoint, make sense to me to do it that way, if you need to be specific about the concentrations.

Mrs. Jane McKenna: Now that you're sitting back thinking about it, did it not cross your mind why it was so matter of fact to you, how you're describing what you would do, how it was not matter of fact for a hospital doing it for the last year, that nobody else had that matter-of-fact attitude?

Ms. Nancy Froude: I ask myself that every day since this happened. Honestly, I think putting the two things together—getting that call from Peterborough saying that there's something different with the label and then looking at the bag and putting those two pieces of information together is what triggered things for me that I'm not sure that this right.

Mrs. Jane McKenna: Right.

Ms. Nancy Froude: And the only way for me to know that was for us to pull things out of the bag.

Mrs. Jane McKenna: Right. Because I think that's our biggest—as we're sitting here, we're trying to figure that out as well. Because, clearly, there was not only a miscommunication somewhere, but someone that has your qualifications was clearly doing that in Windsor hospital, and yet, that's a long time, a year.

Ms. Nancy Froude: Right.

Mrs. Jane McKenna: Okay, thank you very much. That's all I have.

The Chair (Mr. Ernie Hardeman): Okay. Ms. Gélinas?

M^{me} France Gélinas: Continuing on this train of thought, the series of events leads us to believe that it could just as well have gone undetected. You had been using it. What happened in Peterborough looks like a fluke to me, and that had they not called you, had you not put the two pieces together—you come from the retail sector, you started to think, "This is not a very efficient way to mix things because of the overfill"—this could have been undetected. It feels really, really unsettling to think of things like that.

When you do buy drugs like admixtures, what are the checks and balances to make sure that what you get in there is what you're supposed to have?

Ms. Nancy Froude: I don't know, honestly, what the process was in dealing with the company to get that product to us.

M^{me} France Gélinas: But were you taking it for granted that somebody had done the check, it just wasn't your job, or that you don't know if a check exists?

Ms. Nancy Froude: I don't know what checks were done in the process. I think there's also a level of trust that we have when we're dealing with drug manufacturers, that there's a trust that the product that you get is what you're getting. I think we have that trust every time we take a Tylenol or every time we take some cough medicine, that what the company says is on the label is what's in that bottle. I think, as a society, we've come to have that trust in the pharmaceutical industry.

M^{me} France Gélinas: Okay. Did you yourself communicate with Marchese at all?

Ms. Nancy Froude: Yes, I did.

M^{me} France Gélinas: Can you describe how it happened?

Ms. Nancy Froude: Prior to March 20, we did have some concerns with a shipment of pamidronate that came to us just in regard to the storage direction that was given on the label for the pamidronate.

M^{me} France Gélinas: And what were those concerns and how were they settled?

Ms. Nancy Froude: The pamidronate that we had been receiving previously we were storing in the refrigerator according to that manufacturer's guidelines. When we got the pamidronate from Marchese, it actually was labelled just to store at room temperature.

M^{me} France Gélinas: And how was it settled? Was it because—

Ms. Nancy Froude: Through a series of phone calls that were made by myself to Marchese and to the company that we had previously been receiving it from.

M^{me} France Gélinas: And did you end up putting it back in the fridge, or did it stay at room temperature?

Ms. Nancy Froude: It's at room temperature.

M^{me} France Gélinas: It's at room temperature.

Ms. Nancy Froude: Well, we're no longer using it, so it's—yes.

M^{me} France Gélinas: So that was part of the four drugs that you were getting premixed. You're now doing all four of those drugs in-house?

Ms. Nancy Froude: We are, yes.

M^{me} France Gélinas: Does that involve more work for you or for members of your team?

Ms. Nancy Froude: It does not make more work for me, personally, but definitely makes more work for our team.

M^{me} France Gélinas: And how are they coping with it?

Ms. Nancy Froude: Some overtime, and also relying on the main pharmacy within the hospital to do some extra work for us.

M^{me} France Gélinas: Okay. If you think back to checks and balances—you come from an environment that had college supervision, that had oversight, checks and balances—where do you think would be the reasonable place to have this kind of oversight done?

Ms. Nancy Froude: I think there are probably several steps along the way. I was not aware that the college was not inspecting or regulating these companies that were doing these admixtures for hospitals. I think that absolutely needs to be done to ensure that there are standards being met there. I think that was kind of something—a big point that was missed in that step of the safety chain of the drugs, definitely. Also, I think that having that college inspection done at every hospital pharmacy is essential, too, to make sure that standards are being met and maintained.

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M^{me} France Gélinas: Not only the outpatient but also the regular pharmacy of the hospital, you figure, should have oversight?

Ms. Nancy Froude: I do, yes.

M^{me} France Gélinas: Okay. I'm not a pharmacist. Some of them are; not I. The issue of drugs being concentration-specific vs. non-concentration-specific: Is this something that is always on your radar when you work, or is this a one-off specific to oncology?

Ms. Nancy Froude: I'd say it's fairly specific to oncology, because we are using those products differently than, let's say, an antibiotic. An antibiotic bag is made, and the entire bag is run; although concentrations need to be looked at, they're not really as important, because that whole bag is being given. If there is a gram of an antibiotic in a bag, whether it's in 100 millilitres or 104 millilitres doesn't make a difference if the whole bag is administered, whereas for chemotherapy we weren't

using those bags in that manner, so the concentrations are imperative.

M^{me} France Gélinas: And do the volumes of medication vary greatly from one person to the next?

Ms. Nancy Froude: The doses?

M^{me} France Gélinas: The doses, yes.

Ms. Nancy Froude: Yes, because it's dosed according to height and weight. Even for one type of cancer compared to another type of cancer, the doses may be different. For example, one regimen may say that they get 100 milligrams per metre squared; another regimen may only say 50, so there are different doses depending on what disease you're treating. Often we'll do dose reductions for chemotherapy, based on how patients are tolerating chemotherapy. Sometimes we'll only give half of the recommended dose if they're having a lot of side effects or not tolerating. So there can be a wide range of dosing.

M^{me} France Gélinas: Would what you shared with me be considered basic knowledge for pharmacists working with oncology? You would know that dosages vary greatly and you need to pay attention to the concentration so that you get the right dosage for the right patient at the right time?

Ms. Nancy Froude: Exactly. Like I said before, if you're not working in oncology, even if you're handling those drugs, as a pharmacist, you need to be familiar with what you're handling.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time. To the government side: Ms. Mangat?

Mrs. Amrit Mangat: Thank you, Chair. Thank you, Nancy, for your presentation. Given your experience, since you have worked in various community pharmacy settings, from independent, private pharmacies to big chain stores, including hospitals, can you share with the members of the committee what kind of process checks are normally undertaken in the preparation of compounded drugs?

Ms. Nancy Froude: I'm sorry; could you just repeat the last—

Mrs. Amrit Mangat: What kind of process checks are normally undertaken in the preparation of compounded drugs?

Ms. Nancy Froude: If we're compounding drugs for our own use—so, what we're doing now, basically, right?

Mrs. Amrit Mangat: Yes.

Ms. Nancy Froude: We have a series of worksheets our technicians will use. There's always a double- and triple-check of volumes and the drug product itself, what's being added—there are lots of checks along the way, so there's never just one person making something. Things are always initialled by two technicians in that process.

Mrs. Amrit Mangat: Are there any guidelines or policies with regard to that?

Ms. Nancy Froude: Within our program in oncology, we do have a set of pharmacy guidelines that will state that.

Mrs. Amrit Mangat: What other quality insurance measures are in place, other than guidelines and principles?

Ms. Nancy Froude: Like I said, we have multiple checks along the process of making those products, and various safety things put in place. For example, we'll only have one drug in the hood at a time. Multiple people are looking at what's going in and what's coming out after it's made.

Mrs. Amrit Mangat: Are you confident in the safety of the drug supply which was being supplied at the Durham Regional Cancer Centre?

Ms. Nancy Froude: What we're making ourselves?

Mrs. Amrit Mangat: Both what you are making yourselves, or whether it was given by Marchese or Baxter.

Ms. Nancy Froude: I'm confident in what we're making ourselves because I know the staff who are working, and they're very committed, proficient individuals who have had a lot of years of experience in pharmacy and in chemotherapy.

As far as what's being outsourced, I'm not sure that my opinion is what it would have been three months ago, but I am still confident in what's coming from outsourced pharmacies.

Mrs. Amrit Mangat: So why is it important that drugs should be removed or quarantined? Why is it important to remove the drugs or to quarantine the drugs?

Ms. Nancy Froude: So not to continue using Marchese?

Mrs. Amrit Mangat: Yes.

Ms. Nancy Froude: Mostly because the volumes are going to be so inconsistent now, we'd have to pull everything out of every bag. It's also not safe for us to do that.

Mrs. Amrit Mangat: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. To the opposition: Any further questions? If not, that concludes the time.

M^{me} France Gélinas: Can I ask one quick question?

The Chair (Mr. Ernie Hardeman): You'd have to ask for time from the other parties.

M^{me} France Gélinas: Can you give me a minute? When you were talking about the monograph, who enters that into the computer, and how often is it checked? When you get a new—I don't know how this thing is done.

Ms. Nancy Froude: We do have staff members who are dedicated—that's part of their role to do that. I'm not one of them, so I'm really not sure what all their safety checks and processes are.

M^{me} France Gélinas: But would it be done every time you have a batch, every shift, every 24 hours? How often are those entered?

Ms. Nancy Froude: The drugs would only be entered when we start using them. So each drug entry would just be done once, and then it stays in the computer system.

M^{me} France Gélinas: Unless it's changed.

The Chair (Mr. Ernie Hardeman): Thank you very much. It's like a photographer that says, "Just one more, just one more." But we do thank you very much for participating this afternoon. I'm sure you've been of great assistance to the committee. Thank you very much.

Interjection.

The Chair (Mr. Ernie Hardeman): We'll just wait a moment. The next witness is on her way up from the basement. She should be here momentarily.

MS. LAURA SAVATTERI

The Chair (Mr. Ernie Hardeman): I think our next delegation has arrived: Laura Savatter. If you want to take a seat at the head table there. Good afternoon, and thank you very much for being here.

Ms. Laura Savatter: Thank you. Good afternoon.

The Chair (Mr. Ernie Hardeman): As with all the delegations that we've been hearing from, you will have 20 minutes to make your presentation. It goes along with a thank you for being here. Then each caucus will have an opportunity for 20 minutes to ask any questions they may have about your presentation and the events that we're referring to. The questioning and the comments this time will start with the third party.

With that, the floor is—oh, you've got to be sworn in. My apologies for the oversight. We'll ask the Clerk to swear you in or to affirm you.

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The Clerk of the Committee (Mr. William Short): It's Ms. Salvatore?

Ms. Laura Savatter: It's Savatter.

The Clerk of the Committee (Mr. William Short): Savatter?

Ms. Laura Savatter: Yes.

The Clerk of the Committee (Mr. William Short): Got it. Did you want to swear an oath or did you want to be affirmed?

Ms. Laura Savatter: I'll swear an oath.

The Clerk of the Committee (Mr. William Short): The Bible's in front of you there. Thank you. Ms. Savatter, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Laura Savatter: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we will start your presentation. The floor is yours.

Ms. Laura Savatter: Thank you, Mr. Chairman. Good afternoon. My name is Laura Savatter. I thank you for the opportunity to address your committee.

I am a pharmacist licensed by the Ontario College of Pharmacists. I am also a member of the Ontario Pharmacists' Association, the Hamilton and District Pharmacists' Association and the National Home Infusion Association. I received a bachelor of science degree in

pharmacy from the University of Toronto in 2009. Since graduating, I have been employed by Marchese Health Care as a registered staff pharmacist.

My passion for pharmacy began in my teens. Before graduating and becoming a pharmacist, I was employed as a pharmacy assistant for seven years at a large retail pharmacy. I was also employed as a pharmacy student by Marchese Health Care.

In addition to my employment, I am involved in a number of community initiatives related to my profession. For example, since 2009, I have been a guest lecturer in the Mohawk College-McMaster University pharmacy technician program. I have also made a number of presentations to health care professionals and patients, as well as primary and secondary school students, on the importance of medication safety. On a weekly basis, I also participate in interprofessional palliative team rounds at a local hospice, and I'm a pharmacist resource to the Hospice Palliative Care Network Advisory Committee.

Between December 2011 and July 2012, I was also interim manager of Marchese Health Care's accredited pharmacy in Kitchener. In that capacity, I oversaw provision of home infusions and medical supplies for home care clients served under a local community care access centre.

I was part of a team of pharmacists and other Marchese staff involved in the start-up of Marchese Hospital Solutions. One of my contributions, a small part of my total responsibilities at Marchese, involved phone calls and email exchanges with Health Canada and the Ontario College of Pharmacists, or OCP. All of those exchanges were conducted professionally and amicably.

Before providing details on these communications, I wish to convey that I am saddened that any person would have to go through the distress caused by this issue. My hope is that we all end up with a better system and a safer system for everyone.

I have prepared a booklet containing, in chronological order, notes and emails relating to my communications with Health Canada and OCP. I understand that some of these communications have already been provided to the committee. I also understand that there may be other email exchanges that I have not yet found. The documents I have provided are the ones I was able to locate and that I believed would be helpful for the committee to understand the nature of our inquiries.

The notes and email exchanges in the booklet focus on my communications with Health Canada and OCP in early 2012. They are email exchanges I was involved in and any notes I made based on my knowledge of telephone conversations.

While I'm aware that Marchese staff also had exchanges with Health Canada and OCP, I can really only speak with confidence about my own communications. I hope the booklet will be helpful to the standing committee's inquiry.

My communications with Health Canada began in early 2012.

My first note, at tab 1(a) of the booklet, reflects my note of a call with a Health Canada representative on January 18, 2012. As I noted, this representative thought we were "manufacturing" and recommended I call Health Canada's Therapeutic Products Directorate, or TPD. The follow-up emails can be found at tab 1(b).

At tab 2 of the booklet you will see my note dated February 1, 2012. I called TPD. After a series of transfers, I was connected to a Health Canada representative from TPD. He told me he believed Marchese's situation was unique. He offered me four contacts who might be in a better position to assist us. I called all four, left messages where appropriate and, in particular, left a message for a compliance specialist in the drug GMP inspection unit of Health Canada's Products and Food Branch Inspectorate.

From my note at tab 3 you will see that on February 7, 2012, I finally spoke with this particular representative. She informed me that there were many unregulated entities conducting similar operations. She named three, one of which was Baxter-CIVA.

In our conversation on February 7, 2012, this Health Canada representative informed me that she understood we were compounding products with DINs, or drug identification numbers, in IV bags. My notes of her initial observation were that we were "manufacturing," but because we were supplying hospitals based on history of patient need, we were "not technically manufacturing." She explained that Baxter-CIVA was doing the same thing, but we were better off because there was a pharmacist on-site.

I will read directly from my note:

"She explained Policy 51—pharmacy can outsource to whomever they want. Her opinion is that the patient-health care professional relationship is still maintained since the pharmacy that cannot provide the product has a relationship with the patients and the outsourced partner has a relationship with that pharmacy and so the relationship is indirect.

"Sarah explained that we generally should not be concerned because it seems that we are doing everything we can from a quality-control perspective and that the worse that can happen is 'compliance and enforcement discretion action': If HC decided we were contravening any regulations, they have the right to shut us down."

You will see from tab 4 that on February 18, 2012, I sent a follow-up email, attaching a document summarizing Marchese's operations. I also asked her for any guidance that could be provided by her or her team.

At tab 5 you will see a copy of the document that I attached to my February 18 email. The document describes Marchese Hospital Solutions' business in detail. The last paragraph describes Marchese's efforts in seeking regulatory guidance. I would like to read the last paragraph to the committee:

"As discussed with Sarah Skuce of GMP unit, at this point, Marchese has entered into many discussions with authorities from Health Canada, the Ontario College of Pharmacists, New Brunswick pharmacy regulatory

bodies, GMP consultants and CanReg to ensure documented due diligence with respect to regulations. It continues to be unclear as to what regulation(s) we will be required to satisfy going forward, as we commit ourselves to navigating this grey area. It is Marchese's intent to meet or exceed quality and regulatory standards to provide excellent products and services that meet patients' health care needs and that uphold the Marchese reputation built over 15 years of providing innovative services to enable better health through better care."

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On February 28, 2012, I sent an additional follow-up email requesting a status update, reminding her that I had also left a voice mail message the week before. That email is found on tab 6 of the booklet.

At tab 7 of the booklet, I have reproduced the response received on March 1, 2012. She told me she had not yet contacted OCP and did not know who she should be speaking with. She also asked for information about Marchese's OCP contact.

Later in the day, I responded by providing a name of a contact at OCP. I also raised the possibility of becoming a facility partially licensed under GMP, if required, and with an OCP accredited pharmacy occupying the other portion of the premises. That email, also dated March 1, 2012, is found at tab 8 of the booklet.

At tab 9 of the booklet, I have provided a copy of a further email I sent on April 5, 2012, requesting further clarification regarding Health Canada regulatory requirements. I re-attached the document at tab 5 previously sent to her on February 18, 2012. I informed her that Marchese had been in contact with the OCP about accreditation of the Mississauga facility. OCP had explained to me that, under policy 0051, Health Canada had the authority to override provincial regulations when it is unclear whether a facility was compounding or manufacturing. I suggested that Health Canada contact OCP directly to discuss the matter. I also suggested a meeting involving Marchese, OCP and Health Canada to expedite the discussion and allow Marchese to move forward with certainty.

On May 8, 2012, I sent a follow-up email to Health Canada requesting dates for a meeting with OCP. That email is found at tab 10 of the booklet.

If you turn to tab 11, you will see that on May 9, 2012, I received a reply from Health Canada stating that she had spoken with her manager about a meeting with OCP. She also informed me that a meeting was scheduled in June between Health Canada and the National Association of Pharmacy Regulatory Authorities, or NAPRA, to discuss policy 0051. Because this Health Canada representative thought jurisdictional decisions could be made at this meeting, she suggested that this meeting occur before meeting with Marchese and OCP.

In her May 9, 2012, email, Health Canada also asked for details of the initial feedback Marchese received from OCP. The Health Canada representative also stated that Health Canada would work with the colleges to ensure that all activities relating to compounding and manufac-

turing had regulatory oversight, but Health Canada did not overrule provincial law or jurisdiction. She stated that if Marchese's operations were compounding, then Health Canada would not have oversight of the facility.

I will now turn to my involvement in communications with the OCP.

At tab 12, you will see an email I sent to OCP on March 21, 2012, requesting information on accreditation of the Mississauga facility as a pharmacy. I also asked for a meeting with OCP representatives to discuss requirements for OCP accreditation. The same day, a description of Marchese's operations and a floor plan were requested.

On March 27, 2012, I sent a floor plan, together with another document, which provided a detailed description of Marchese Hospital Solutions' operations. A copy of my email and its attachments is found at tab 13.

A teleconference was scheduled with OCP on April 3, 2012, involving myself, and other Marchese representatives. I will read directly from my note, which can be found at tab 14:

"The take-home point that OCP feels much the same as HC in that they don't believe that MHS operations falls under their jurisdiction. He explained that based strictly on our Medbuy business, OCP would not accredit us. Greg explained that if we wanted to become an 'accredited pharmacy,' we would need to have patient-specific prescriptions transferred to that site. Therefore, he suggested seeking accreditation based on the plan to move some of our Hamilton business ... to the Mississauga site. He also explained his understanding of policy 51, which was that Health Canada has the authority to override provincial regulations when it is unclear whether a facility is compounding or manufacturing. We later learned from Sarah Skuce that this interpretation is not correct. Lastly, when asked about shipping admixtures to New Brunswick hospitals, Greg stated that he does not believe any of this operation falls under OCP jurisdiction and therefore, he could not comment on it."

At tab 15, you will see a copy of an email I received from OCP on April 26, 2012, regarding an application to open a new pharmacy. The questions were operational in nature, and I provided the answers. This discussion was forwarded to an OCP pharmacy inspector, who confirmed her intention of attending an opening inspection before May 30, 2012.

At tab 16, you will see an email from OCP to the Ministry of Health and Long-Term Care dated June 15, 2012. The email indicated that OCP had accredited a pharmacy, Marchese Health Care in Mississauga.

Through all of these conversations and email exchanges with Health Canada and OCP I have outlined today, Marchese was seeking regulatory guidance. We wanted to know which organization was the appropriate regulatory authority for activities that Marchese staff had described in detail. After participating in these communications and discussing them with the Marchese team, it was my understanding that neither Health Canada nor OCP regarded the activities conducted at

Marchese Hospital Solutions as falling within their regulatory jurisdiction.

If you have any questions, I will do my best to answer them.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. The questions this time will start with the third party. Ms. Gélinas.

M^{me} France Gélinas: Wow. Thank you very much for your presentation. It was easy to follow, it was informative, it was well done. Thank you so much.

Ms. Laura Savatter: Thank you.

M^{me} France Gélinas: I will take you right to the end, where you say, after having done all of this, you made the conclusion, “It was my understanding that neither Health Canada nor OCP regarded the activities conducted at Marchese Hospital Solutions as falling within their regulatory jurisdiction.” Do you remember the date that you came to that conclusion, who was there at the meeting? How did that come down?

Ms. Laura Savatter: That’s an interesting question. It’s difficult for me to decide what date that would have been. What I can tell you is that my primary role was to be an information-gatherer. As I’ve presented today, all of my communications with Health Canada and with the Ontario College of Pharmacists were brought back to the Marchese Hospital Solutions executive team and a corporate decision was made to proceed. But of course, as you know today, that clarification is an ongoing thing.

M^{me} France Gélinas: As you gathered all of that information—much of it you have shared with us—who would you report to at Marchese?

Ms. Laura Savatter: That would be the executive management team.

M^{me} France Gélinas: Could you name them for us?

Ms. Laura Savatter: It would be our general manager and president and CEO.

M^{me} France Gélinas: And who is the general manager?

Ms. Laura Savatter: Ross Kearns.

M^{me} France Gélinas: Is he a pharmacist?

Ms. Laura Savatter: No.

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M^{me} France Gélinas: And who is the president?

Ms. Laura Savatter: Marita Zaffiro.

M^{me} France Gélinas: Okay. And is she a pharmacist?

Ms. Laura Savatter: Yes.

M^{me} France Gélinas: So by the beginning of the summer of 2012, you’ve gone through an extensive amount of effort and energy to try to get those people to look at you. You submit all of this information to the general manager and to the president, and then you’re basically told, “You’ve worked hard enough on this file. This is as far as we’re going to get with those two agencies.”

Ms. Laura Savatter: Well, I have to say that I don’t know that it was black and then white. It was really a continuous communication that was occurring. There comes a point where you’ve gathered quite a bit of information and a corporate decision needs to be made,

taking into account that there are a lot of quality control measures in place.

M^{me} France Gélinas: So you figure that this is what happened? We haven’t got anything past June 2012, and that’s because your role in trying to gather information from Health Canada or from the Ontario College of Pharmacists more or less ended there?

Ms. Laura Savatter: Right. My involvement with Marchese Hospital Solutions at that point had really subsided. I’m actually not an employee of Marchese Hospital Solutions directly; I was serving as a resource at the time, sort of working on that project, but my involvement is at Marchese Health Care in Hamilton.

M^{me} France Gélinas: In Hamilton, okay. Have you ever worked in oncology before?

Ms. Laura Savatter: I have not worked directly in oncology. My IV pharmacy experience personally has to do with servicing of home infusion clients through the Hamilton Niagara Haldimand Brant CCAC contract, and also managing our Kitchener accredited pharmacy to service home infusion clients under the Waterloo Wellington CCAC.

M^{me} France Gélinas: If you came across an admixture, or the company is required to prepare an admixture, of a new drug, how do you become informed about new chemotherapy drugs? What are the tools at your disposal so that you know how it is used? What does a pharmacist do?

Ms. Laura Savatter: What does a pharmacist do? Are you referring to with respect to an accredited pharmacy, where we’re dispensing directly to a patient?

M^{me} France Gélinas: Sure, let’s start there.

Ms. Laura Savatter: If that was the case, there are a lot of different things that the pharmacist would have to consider. First of all, we would evaluate the prescription to make sure that it’s a valid prescription and a valid order. We would take a look at the patient’s clinical parameters, depending on what the drug is. We might look at allergies and concomitant medications, see if there are any drug interactions, see if the patient has any other comorbid conditions that we need to take into account, and then we would see, based on all of those things, if the dose was appropriate. Then, ultimately, how do we ensure that we’re going to mix this product in a manner that ensures sterility and stability? Then, of course, there’s the aspect of patient counselling, to ensure that the patient uses the medication in the most appropriate way.

M^{me} France Gélinas: Very good. Now I’ll take you back—in the notes you have given us, it’s on page 5, but you read it into the record—to where, basically, you’re in conversations with a Health Canada representative. They’re actually getting back to you, which is a nice change, because they seemed to be ignoring you quite often. They say:

“My notes of her initial observation were that we were ‘manufacturing,’ but because we were supplying hospitals based on history of patient need, we were ‘not technically manufacturing.’ She explained that Baxter-

CIVA was doing the same thing but we were better off because there was a pharmacist on site.”

Who was the pharmacist on site who made you better off?

Ms. Laura Savatteri: My interpretation of this conversation is not who the pharmacist is on site, but that there is a pharmacist on site. So she was satisfied—she was commenting on the fact that there would be a registered pharmacist on site supervising the activities.

M^{me} France Gélinas: Okay, and she had known that because, on tab 5, we have the explanation as to how you would be doing the admixing?

Ms. Laura Savatteri: Precisely.

M^{me} France Gélinas: Okay, very good. Then she goes on to say, “Her opinion is that the patient-health care professional relationship is still maintained since the pharmacy that cannot provide the product”—I take it that’s the hospital pharmacy—“has a relationship with the patients”—which is true—“and the outsourced partner has a relationship with that pharmacy and so the relationship is indirect.” Does that make sense to you?

Ms. Laura Savatteri: It makes sense to me in the context of differentiating between compounding and manufacturing. My understanding is that one of the main differences between compounding and manufacturing is the patient-health care professional relationship. I can’t speak on behalf of this Health Canada representative, so I prefer not to speculate on what she meant, but it did mean something to me.

M^{me} France Gélinas: All right. I’m just trying to understand what she’s saying. When she’s explaining policy 0051 to you in order to justify that you are not manufacturing, the justification is based on the fact that there is always a patient-professional relationship, though an indirect one. Is this what this is saying?

Ms. Laura Savatteri: That would be my understanding.

M^{me} France Gélinas: Knowing how Marchese health solutions works, tell me how this link is actually made.

Ms. Laura Savatteri: Sure. Marchese does not batch admixtures in bulk. What Marchese does is make to a hospital-specific order. For example, if hospital X goes through admixture Y five admixtures per week, they will order five of admixture Y from Marchese hospital per week.

M^{me} France Gélinas: All right. But then the patient relationship is sort of lost there because the hospital does not necessarily require it per patient; it requires it for a group of patients.

Ms. Laura Savatteri: It’s based on a trend. What the hospital does is they order—my understanding of what a hospital does is, they order based on a trend of usage.

M^{me} France Gélinas: For the different patients that come through weekly or—

Ms. Laura Savatteri: Right.

M^{me} France Gélinas: Do you know if you ship weekly? How often do you send those products out?

Ms. Laura Savatteri: As I’ve mentioned, I’m not an employee of Marchese Hospital Solutions, but my

understanding is, for a particular hospital, an average of one to three shipments a week.

M^{me} France Gélinas: That many, eh?

Ms. Laura Savatteri: Right.

M^{me} France Gélinas: Okay. Are you familiar at all with the drug cyclophosphamide?

Ms. Laura Savatteri: Cyclophosphamide: I have some familiarity.

M^{me} France Gélinas: Any idea what the dosage for this drug would be for people undergoing chemotherapy?

Ms. Laura Savatteri: Marchese Hospital Solutions prepares admixtures for these hospitals based on specifications in the contract. The expectation is that the health care professionals at the hospital would know how to prescribe, dispense and administer it appropriately for that patient, if appropriate.

M^{me} France Gélinas: The specification in the contract—who at Marchese would be negotiating that or would be reviewing that to make it make sense?

Ms. Laura Savatteri: Sorry, can you rephrase the question?

M^{me} France Gélinas: You talk about Marchese preparing the admixture based on specifications in a contract.

Ms. Laura Savatteri: Right.

M^{me} France Gélinas: Who at Marchese has the clinical knowledge to understand those specifications in a contract? I’m trying to understand.

Ms. Laura Savatteri: Right. The role of the pharmacist team with respect to Marchese Hospital Solutions is to provide the contractually specified admixtures in a manner that ensures sterility and stability.

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M^{me} France Gélinas: So it would be a team made up of—

Ms. Laura Savatteri: A team made up of pharmacists and also a team made up of pharmacists at Medbuy and with the knowledge that the admixtures are ultimately being dispensed to patients at a hospital level.

M^{me} France Gélinas: There would be pharmacists at Marchese dealing directly with pharmacists at Medbuy to make sure that they understand the specifications of the contract.

Ms. Laura Savatteri: Right.

M^{me} France Gélinas: The same thing with the way the labels are prepared: Who negotiates those—what they want, how they want the labels prepared?

Ms. Laura Savatteri: I was not involved in the RFP phase. My involvement with Marchese Hospital Solutions occurred after that. But what I do know is that Medbuy had requested, prior to start-up, that Marchese Hospital Solutions submit a final label set that would be used for all of the admixtures so that they could approve them and distribute them to all of the health care professionals at the hospital level for training and education purposes. If anybody had any questions at that time, Marchese was open to discussing and addressing them.

M^{me} France Gélinas: I’ll let it go.

The Chair (Mr. Ernie Hardeman): Okay. Thank you very much. The government side: Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Ms. Savatter, you are an accredited pharmacist, as you've told us. If you are presented with the request to provide four grams of gemcitabine in 100 millilitres, how would you do it?

Ms. Laura Savatter: Are you referring to the preparation?

Ms. Helena Jaczek: I'm just asking you a general question. How would you prepare that four grams of gemcitabine in 100 millilitres of sodium chloride.

Ms. Laura Savatter: Are you referring to the admixing of the product?

Ms. Helena Jaczek: Yes.

Ms. Laura Savatter: Okay. I can walk you through that, although that is not my direct area of expertise; I've never actually mixed any of these myself. But if you wanted four grams in 100 millilitres of gemcitabine, typically what would happen is, you would get a two-gram gemcitabine vial. It needs to be reconstituted with 50 millilitres of normal saline. So we would have two two-gram gemcitabine vials and we would have a 100-millilitre pre-filled normal saline bag—

Ms. Helena Jaczek: When you say “pre-filled,” could you specify? Do you mean pre-filled with 100 millilitres or with some other quantity?

Ms. Laura Savatter: Pre-filled with 100 millilitres plus whatever the manufacturer's overfill is on that bag.

Ms. Helena Jaczek: Why would you include the overfill?

Ms. Laura Savatter: It's a pharmacy standard that all pre-filled bags contain a certain amount of overfill. That's actually a manufacturer specification to take into account fluid evaporation over time.

Ms. Helena Jaczek: So that's the way you would prepare this product?

Ms. Laura Savatter: Correct, if I was asked for four grams in 100 millilitres.

Ms. Helena Jaczek: So it wouldn't be 100 millilitres but—

Ms. Laura Savatter: It's a nominal amount. Unless it was specified for it to be 40 milligrams per millilitre or 38 milligrams per millilitre.

Ms. Helena Jaczek: What's the difference between four grams per 100 millilitre and 40 milligrams per millilitre?

Ms. Laura Savatter: Four grams in 100 millilitres does not specify a degree of specificity with regard to concentration. If a concentration is explicitly stated in the requirement of the product, what you would typically see was a greater level of specificity on the label and in the weight of the product, as prepared.

Ms. Helena Jaczek: I personally find that very puzzling. To me, four grams per 100 millilitres is a concentration. So I'm very, very surprised that you feel that way.

As you have probably heard if you've been consulting Hansard in this regard, since the hospitals have gone

back to doing their own admixing, they are, in fact, ensuring that there are 100 millilitres of the diluent. That's how they're doing it.

When they saw this particular request through Medbuy, who was the pharmacist responsible for outlining how this product would be admixed?

Ms. Laura Savatter: I don't know that I can answer that question, to be honest with you. I don't know the answer to that.

Ms. Helena Jaczek: Who was the pharmacist on site, then, at Marchese Hospital Solutions?

Ms. Laura Savatter: The current pharmacist on site wasn't there at the time, so that wouldn't be—and to answer that question is not within my direct knowledge.

Ms. Helena Jaczek: Mr. Chair, I'll be requesting the name of that pharmacist.

The Chair (Mr. Ernie Hardeman): Yes, okay.

Ms. Helena Jaczek: In terms of your frustrations with Health Canada and the Ontario College of Pharmacists—I think we can understand, through your numerous tabs, that you did try to explain your situation and you were getting some conflicting answers, but I do have a question in relation to your inquiry under tab 5, “Inquiry: Marchese Hospital Solutions,” in the second paragraph. This is presumably when you were involved as the pharmacist attempting to assist Marchese. At the end of the second paragraph, you say, “[W]e plan to prepare such admixtures pursuant to a prescription by the hospital pharmacist through our accredited pharmacy.” Could you just explain that to us? Were you envisaging this on a per-patient basis? What exactly do you mean by that plan?

Ms. Laura Savatter: What was meant by this is that any admixtures—actually, if you don't mind, I'd just like to reread this to make sure that I'm answering your question appropriately.

M^{me} France Gélinas: Remind me where we are.

Ms. Helena Jaczek: It's in the second paragraph; tab 5.

M^{me} France Gélinas: Okay.

Ms. Helena Jaczek: Towards the end of the second paragraph.

M^{me} France Gélinas: “We are currently working”—

Ms. Helena Jaczek: “In the interim 4-6 month period, we plan to prepare such admixtures pursuant to a prescription by the hospital pharmacist through our accredited pharmacy.” I just want to get an understanding of what that actually meant, what was envisaged by this.

Ms. Laura Savatter: Okay. At this point, a corporate decision was made to provide controlled substances and narcotics containing admixtures through an accredited pharmacy and to ensure safe tracking and inventory.

Ms. Helena Jaczek: And that would be on a per-patient basis?

Ms. Laura Savatter: Not on a per-patient basis. The word here “prescription” is not a patient-specific prescription. It's a prescription written for a hospital by a hospital pharmacist.

Ms. Helena Jaczek: So there was no intention to provide chemotherapeutic agents in this way?

Ms. Laura Savatter: No.

Ms. Helena Jaczek: Okay. Thank you.

Going back to the decision, can you explain the process to us a little bit? If you are not familiar with the name of the pharmacist who was responsible for initiating the process of admixing gemcitabine, perhaps you could explain to us: Presumably a pharmacist said, "You will take a Hospira bag of saline and you will add four grams of gemcitabine." Presumably somebody said that to some technician who would actually do the preparation. There's no thought that a pharmacist actually prepared the admix solution; correct?

Ms. Laura Savatter: Correct.

Ms. Helena Jaczek: So there was some sort of direction given from a pharmacist: "This is the way you're going to do it." Would that be a correct assumption?

Ms. Laura Savatter: All of the mixture breakdowns or formulae are prepared by pharmacists, and the actual execution of the mixing occurs by an infusion technician who is well trained.

Ms. Helena Jaczek: So presumably once that initial process was decided upon by the pharmacist, in that time it was done the same way and nobody questioned it at Marchese. It was just "the way we do gemcitabine."

Ms. Laura Savatter: Right, and there was opportunity also for questions from Medbuy and from any of the hospitals as well.

Ms. Helena Jaczek: Why would they question it? They were assuming they were getting four grams per 100 millilitres.

Ms. Laura Savatter: I can't speculate as to why they would question it, but they might because the labels looked a little bit different or whatever.

Ms. Helena Jaczek: I don't think they were particularly interested in that, but anyway—let's just go back in time. When did Marchese Hospital Solutions start providing the admixed compound to hospitals? What was the first batch that was sent out?

Ms. Laura Savatter: Mid-February 2012.

Ms. Helena Jaczek: While you were doing all this negotiation between Health Canada and the Ontario College of Pharmacists trying to find out how to regulate, you were already sending this product out to hospitals?

Ms. Laura Savatter: Actually, the communications began in November 2011, and that was not by me. That was another individual within Marchese. They continued, and mid-February is when we started to actually send out the admixtures. At that time, there had already been a lot of information gathered from the regulatory bodies, but there did come a point, yes, where a decision was made by the executive team on how to proceed.

Ms. Helena Jaczek: Thank you. That'll be all for now. We'll reserve our time.

The Chair (Mr. Ernie Hardeman): Thank you. The official opposition: Mr. Yurek.

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Mr. Jeff Yurek: Thank you, Chair. Thanks for coming in today. Just a few questions I have for you before I

turn it over. Were you involved at all with the contract negotiations with Medbuy?

Ms. Laura Savatter: No.

Mr. Jeff Yurek: Have you ever been involved with Medbuy?

Ms. Laura Savatter: I've had some conversations with Medbuy, yes.

Mr. Jeff Yurek: In regard to?

Ms. Laura Savatter: At the beginning of the transition, reaching out to some of the hospital members with regard to logistical activities, total quantity per case and things like that. Throughout the transition, there were many conversations that took place.

Mr. Jeff Yurek: Tell me about the transition. How did that proceed, as far as you were involved?

Ms. Laura Savatter: The transition began, I believe, at beginning of January, and the start-up was—it was about mid-February. I'm not sure what—do you have any specific—

Mr. Jeff Yurek: What occurred between Marchese and the hospitals and Medbuy? Was there interaction amongst the three, or just the two?

Ms. Laura Savatter: One of the things that happened was, all of the hospital directors were reached out to. It was an introductory phone call that took place to introduce who Marchese Hospital Solutions was, what we were going to do, that we would be the new contract provider and to ask what types of products they would be interested in, even though we had an idea. They were mostly logistical conversations: what days they would prefer to order etc. There were negotiations and things that occurred with Medbuy, and I wasn't involved in those.

Mr. Jeff Yurek: Was there ever a time where Medbuy, Marchese and the hospitals were on the same call or same meeting with this transition, or was it—

Ms. Laura Savatter: Not during the transition.

Mr. Jeff Yurek: Where do you think the Ministry of Health should fall in this process? You've talked to Health Canada; you've talked to the College of Pharmacists. Where should the Ministry of Health have been in this, if at all?

Ms. Laura Savatter: I'm not sure how to best answer that question, but I can tell you that there's definitely a need for more clarity in the process. Perhaps that's something that the Ministry of Health could help with.

Mr. Jeff Yurek: Were you shocked that they weren't involved at all?

Ms. Laura Savatter: I can't say that I have an opinion on that, to be honest with you.

Mr. Jeff Yurek: You've looked at the contract given out. What are your thoughts on the details of the contract?

Ms. Laura Savatter: I haven't really looked at the details of the contract, to be honest with you.

Mr. Jeff Yurek: How about the list of products available?

Ms. Laura Savatter: Knowing now, with what's been happening lately, there could be more room for clarity in the future.

Mr. Jeff Yurek: Was there ever an opportunity for clarity on either Medbuy, hospitals or your part that you know of?

Ms. Laura Savatter: If there was a question that needed to be asked, it would have been asked.

Mr. Jeff Yurek: You think there are just a lot of assumptions that went on?

Ms. Laura Savatter: There could have been a lot of assumptions. I can tell you that there are questions that came up in general with certain products when something really stood out. But with respect to gemcitabine and cyclophosphamide, I don't know that there were any questions—at least, none to my knowledge.

Mr. Jeff Yurek: How would that be resolved if there was an issue? Would that be between Marchese and Medbuy, or Marchese and the hospital?

Ms. Laura Savatter: It would depend on the situation. If a hospital had brought an issue to Marchese's attention, Marchese would have addressed it almost immediately but in collaboration with Medbuy. It could really work either way. It could be that a hospital brings it to the attention of Medbuy; Medbuy brings it to the attention of us. But there should always be that loop.

Mr. Jeff Yurek: Did Medbuy have a process laid out for the hospitals in order to facilitate questions or comments to Marchese?

Ms. Laura Savatter: I don't have an in-depth knowledge about that.

Mr. Jeff Yurek: Thanks.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Elliott?

Mrs. Christine Elliott: Thank you very much, Ms. Savatter, for appearing today. I just have a few questions. One is that you've given us copies of emails that went back and forth between yourself and Health Canada. There was an indication at tab 11 that there was going to be a face-to-face meeting in June between Health Canada and the Ontario College of Pharmacists. Do you know if such a meeting ever took place?

Ms. Laura Savatter: The idea is that in June there was going to be a meeting between Health Canada and NAPRA and its registrars. Because at that meeting this Health Canada representative felt that jurisdictional decisions may be made, that was the reasoning for postponing a meeting between Marchese, Health Canada and the Ontario College of Pharmacists. I don't know the results of that meeting, to answer your question.

Mrs. Christine Elliott: Was there a specific decision made internally at Marchese as a result of that June 15 email that that was going to be the end of things, that there was no clear jurisdiction, that you were just going to carry on?

Ms. Laura Savatter: At the end of May there was a pharmacy accredited in Mississauga, so that was part of a corporate decision that was made on how to move forward.

Mrs. Christine Elliott: You've indicated that you haven't read the contract between Marchese and Medbuy. Did you have anything at all to do with the imple-

mentation and the decisions that were made about the admixture preparation process?

Ms. Laura Savatter: I was involved at some level with a group of pharmacists.

Mrs. Christine Elliott: Can you tell us what your involvement was?

Ms. Laura Savatter: Sure. I'm trying to think right now; it just seems like so long ago. Basically there were lots of different activities. My main activity was to communicate about the regulatory jurisdiction aspect that I've talked about today, working with the pharmacists on some of the mixture breakdowns and asking questions to Medbuy when a question was had—that type of thing.

Mrs. Christine Elliott: Was there ever a discussion about the mixture process itself and whether you would use the standard bags or whether you would be drawing from the bags the specific amounts, the specific 100 millilitres that would be used? Any discussions regarding preparation?

Ms. Laura Savatter: No.

Mrs. Christine Elliott: Or any discussion regarding proposed use, whether it would be single-use or multi-use?

Ms. Laura Savatter: No.

Mrs. Christine Elliott: You indicated that there was a label set that was submitted to Medbuy as part of the process of receiving the contract. Do you know if that label set was the one that was actually used?

Ms. Laura Savatter: To my knowledge, it was.

Mrs. Christine Elliott: So there were no changes made to the label set—

Ms. Laura Savatter: Are you referring to the final label set that was sent prior to start-up?

Mrs. Christine Elliott: Yes.

Ms. Laura Savatter: Yes. As far as I know, there were no changes.

Mrs. Christine Elliott: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. McKenna?

Mrs. Jane McKenna: Yes, I just have a couple of questions. Just to get clarification, you were the facilitator, the mediator, back and forth on these emails. Correct?

Ms. Laura Savatter: Yes.

Mrs. Jane McKenna: Okay. What would have been your job description, to be able to have all that knowledge to go back and forth? Would you not have had to look at the contract and see exactly what you were—I'm just curious about how you would know this information if you didn't have all those facts in front of you.

Ms. Laura Savatter: I'm definitely not a regulatory expert or a lawyer. I'm a pharmacist by background, and my job at the time was to be the pharmacy manager of our Kitchener location. I had infusion experience, but I don't know that that's necessarily what drove the role that was given to me. From a resource perspective, I was available, and I was told that I had strong communication skills and so I could carry out that function. I was not a decision-maker in the process; I was simply there to gather information.

Mrs. Jane McKenna: First of all, Marchese came to Medbuy because Medbuy—as far as they understood out there, Baxter was the only one that could facilitate what they needed, so they didn't put an RFP out there. I think if someone is giving you that role of a communicator—to communicate is great, but knowledge is wealth, so you have to be able to have both of those things. When you are the communicator back and forth, and being a brand new company that has never done this before, did you not feel it was your responsibility to have all of that knowledge? You were given that role for a reason; you would have had a job description of what that was. Would you have not, stepping out of it now, realized that maybe there was more knowledge that you should have had going into this process?

Ms. Laura Savatter: To be honest with you, I don't know that reading the contract would have helped with any regulatory jurisdictional questions. I worked very closely in reporting back and forth to senior management and executive management, who had all of that knowledge. I was providing information, and it was a very open communication. I don't know that the words in the contract would have been specific to that.

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Mrs. Jane McKenna: Okay. So now that you're through the process—I mean, I'll say this over and over again: When I get out of a situation, I can digest what has usually happened and wish I had said things clearly at the time that sound great after it's over, which I would have really said. What do you feel could have been done differently at your end?

Ms. Laura Savatter: Can you rephrase? Are you referring specifically to the regulatory—

Mrs. Jane McKenna: Yes.

Ms. Laura Savatter: To be quite honest with you, I feel that Marchese—with all of the information and knowledge that we had at the time, I feel that we did our best to try to get the answers that we needed.

Mrs. Jane McKenna: Okay. I'm just saying this because we're going back and forth here. When you're first-hand on anything and you've never done any of this before, I would make sure that all the people who were dotting the i's and crossing the t's were being very specific of what—I wouldn't be speculating or guessing or maybe not enough communication or whatever that is. To me, I would have had everything in stone—who was asking what, specifically—so that there wouldn't be any overlap, any confusion at all.

Even speaking with you here today, I'm confused, as a person that is not a pharmacist, and by no means do I attest to be that at all. I just think that if I was in that position and there were so many grey areas and so many things that are clearly high-alert—how there weren't people being more specific that were in the situations that we are, like yourself, to ask those questions. If you don't have the knowledge to ask the questions, how are you going to know the questions to ask, I guess is what I'm saying.

Ms. Laura Savatter: Sorry, I'm unclear. What knowledge are you referring to not having?

Mrs. Jane McKenna: When you were going back and forth in all the tabs here—at the end result, when you were finished with everything you were doing, getting to the point, I guess, of meeting whoever that was, on what tab that was—I apologize. Do you feel that all the questions and all the things that you did from tab 1 up to tab 16 was everything you possibly could have done with what you had?

Ms. Laura Savatter: I honestly believe that we provided every detail of our operation. I do believe that we tried our best to try to understand what jurisdictional scope we might fall under.

Mrs. Jane McKenna: Okay.

The Chair (Mr. Ernie Hardeman): Okay. Ms. Gélinas?

M^{me} France Gélinas: I want to come back to some of the comments that you made regarding concentration. Am I right in thinking that if we had asked Medbuy to prepare gemcitabine at 40 milligrams per millilitre rather than 40 grams per 100 millilitres, that we wouldn't be here today?

Ms. Laura Savatter: I would guess not.

M^{me} France Gélinas: And same thing goes for cyclophosphamide: Had we asked for 20 milligrams per millilitre rather than four grams per 200 millilitres, you and I would have never met?

Ms. Laura Savatter: I would guess not.

M^{me} France Gélinas: All right. Marchese lost a big contract. All of those hospitals high-tailed it back to the security of their own pharmacies and are now mixing those drugs themselves. With this committee going on, and Dr. Thiessen going on, I cannot see the day where they will feel comfortable going out again. What is the learning that Medbuy is taking from this?

Ms. Laura Savatter: I prefer not to speculate. I don't know what learning Medbuy would take from this.

M^{me} France Gélinas: No, I meant to say Marchese. I'm really sorry. I said Medbuy; I meant to say Marchese. I'm sorry.

Ms. Laura Savatter: That's okay. I think the learning from Marchese, and probably the learning from everybody, is that there can be more clarity in the process. I think that one of the things that, really, we would need to answer your question more intelligently is to really see the results from the investigation of Dr. Thiessen. I'm really happy about the fact that he's getting to analyze every aspect of this drug supply chain. I do think that, ultimately, a national labelling standard would be paramount.

M^{me} France Gélinas: That makes sense.

On the label from Marchese that was shared with us—I don't know if it's because I don't know how to read it—we don't see a best-before date. Is it your understanding that it should always be there?

Ms. Laura Savatter: Absolutely.

M^{me} France Gélinas: Is it because I don't know how to read those things?

Ms. Laura Savatter: It's probably because it's blank, because it depends on the day that it's made. So, if it's 30 days from that day, it's written when it's prepared.

M^{me} France Gélinas: Oh, I see. So the labels that were copied to us were generic labels before a solution was actually made, and once a solution is made, it will be stamped with that date on it?

Ms. Laura Savatteri: I would presume so. I'd have to see it, but yes.

M^{me} France Gélinas: Okay. It sort of makes sense.

Every pharmacist who has stood in front of us talked to us about how basic concentration of medication is; that as soon as you start your training, you're taught—somebody teaches you about the importance of concentration versus total amount. It seems to vary greatly from one medication to the next, but it always seems to be something that you guys talk about. Am I right? Is it that basic that when you talk about medication, a flag would always go up as to, "Does this need to be concentration-specific or not," or is this something really out of the ordinary for you?

Ms. Laura Savatteri: Well, it's not out of the ordinary. "Concentration" is a commonly used term in pharmacy, and every pharmacist would have an understanding of concentration, I would presume. Of course, it depends on the situation, it depends on the information given on the drug in question etc.

M^{me} France Gélinas: Did you want to go with your questions?

Ms. Cindy Forster: I've asked this question, actually, of a number of people who have been here to present over the last couple of weeks. The fact that Marchese thought they were preparing a stock drug for one patient, a single-patient dose: Should a red flag have been raised, in particular with respect to the amount of drug in a 100-millilitre bag or in a 200-millilitre bag, having heard from a number of witnesses that the dosage in those bags actually exceeded any dose for any patient who had ever had those drugs administered?

Ms. Laura Savatteri: That's a good question. What I can tell you is that Marchese Hospital Solutions has prepared admixtures as specified in the contract. The role of Marchese Hospital Solutions staff is to ensure that we're providing a sterile and stable product according to specifications. If at any time there was a question asked from a hospital about a dose, we have the ability to look that up. But there is an expectation that these admixtures are going to be appropriately prescribed and dispensed, and administered by the appropriate health care professional to the appropriate patient in the hospital setting.

Ms. Cindy Forster: Someone—I think it was my colleague from Nickel Belt, Ms. Gélinas—asked what the role of the pharmacist was, and in your experience, you said that one of those roles was in fact checking the prescription for the appropriate dosage. Do you not think that Marchese, having had a pharmacist on site, it was part of his role to ensure, if the contract was for a one-patient dose order, that it was in fact an appropriate dose of medication in the minibags?

Ms. Laura Savatteri: That's also a great question. My answer is that prescriptions are patient-specific. Marchese Hospital Solutions is providing an admixture

based on an admixing service to a hospital. It's a very unique type of situation, and in fact the pharmacist is working in a much different capacity; in a different role, a much more technical role. It is not necessarily a clinical role, because the pharmacist does not know the patient, does not know the prescriber and is not privy to any of the clinical parameters surrounding that particular patient.

What the pharmacist is doing in that regard is acting as an intermediary between Medbuy and the hospital, so we're not privy to how the drug will be administered ultimately.

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The Chair (Mr. Ernie Hardeman): Okay, that concludes the time for the third party. Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Ms. Savatteri, knowing as you did intimately that there was this regulatory grey zone, as we've heard, and following up a bit on what Ms. Forster has just asked you, would you not think, as a pharmacist, that there might be an extra burden, perhaps, on Marchese Hospital Solutions to be extra, extra careful that in fact the contract was being adhered to in the way that the purchaser—in this case, Medbuy—intended? It strikes me that you were aware there was a grey zone, so I would have wondered if you would not feel that perhaps you would want to be extra careful in a situation like this.

Ms. Laura Savatteri: I think the entire team wants to and continues to be extra careful. One of the things that Marchese Hospital Solutions does really well is just that. It's a state-of-the-art facility where there's a lot of compliance with what's called USP 797 practices. It's a highly sterile environment. There are a lot of quality control processes, from the minute an order is received to the minute it leaves the door, to ensure its sterility. Those are the types of technical quality assurance measures that take place. As you've mentioned, it is all in accordance with the contract.

One of the important things here is that because there are so many health care professionals involved in this practice, there's always an openness to communication. If an issue had been raised, Marchese Hospital Solutions, I believe, would have been happy to address it.

Ms. Helena Jaczek: As far as you know, did anyone from Marchese, perhaps the pharmacist that was responsible for the first admixture of these two chemotherapeutic agents—as far as you know, was there any phone call from Marchese back to Medbuy to say, "You haven't provided us with a specific concentration," in the way that you look at it per millilitre as opposed to per 100 millilitres? Was there any communication back to Medbuy to inquire as to what the meaning of that was?

Ms. Laura Savatteri: No. I have no knowledge of that.

Ms. Helena Jaczek: Okay. In terms of your role now as a pharmacist on staff at Marchese Hospital Solutions—

Ms. Laura Savatteri: Marchese Health Care.

Ms. Helena Jaczek: Marchese Health Care?

Ms. Laura Savatter: Right. I'm not employed by Marchese Hospital Solutions. I had a limited involvement during that time.

Ms. Helena Jaczek: I see. Now you're at Marchese Health Care, which is an accredited pharmacist.

Ms. Laura Savatter: Correct.

Ms. Helena Jaczek: In terms of what we've heard from other individuals in these hearings, there was a feeling that it was not reasonable that one patient would receive the entire 100-millilitre or 107-millilitre or 111-millilitre bag. As a pharmacist, do you have any opinion as to whether that was a reasonable dose?

Ms. Laura Savatter: I have no opinion, but what I do know is that from my understanding, there was no information to indicate that multiple patients would be receiving one admixture.

Ms. Helena Jaczek: I see. And as far as you know, again, nobody went to a textbook and looked up what a reasonable dose was?

Ms. Laura Savatter: I can't comment on that.

Ms. Helena Jaczek: Okay, thank you. In terms of your involvement when the phone call came in from Peterborough, were you one of the people who was at the end of the phone when Peterborough phoned?

Ms. Laura Savatter: No.

Ms. Helena Jaczek: Who was?

Ms. Laura Savatter: The pharmacist on site.

Ms. Helena Jaczek: Who is? What is the name? We're having so much trouble keeping—

Ms. Laura Savatter: I can provide her name to the Clerk at a later date, if that's okay.

Ms. Helena Jaczek: Yes. This is the person at Marchese?

Ms. Laura Savatter: Right.

Ms. Helena Jaczek: In terms of what has happened since, have you been involved in terms of Dr. Jake Thiessen's investigations?

Ms. Laura Savatter: Yes. I've spoken to him on a couple of occasions.

Ms. Helena Jaczek: And you've explained the situation as you have to us: that it was your understanding that it was four grams in a 100, plus or minus, bag.

Ms. Laura Savatter: The Marchese team had explained that to him.

Ms. Helena Jaczek: Okay. So your role, really, was very much on the side of this regulatory grey zone.

Ms. Laura Savatter: Correct.

Ms. Helena Jaczek: What do you think about those particular regulations that have been put in place since this incident occurred? Do you have any opinion related to how this might safeguard the supply?

Ms. Laura Savatter: I do think that we're heading in a positive direction. I think there may be an opportunity for more clarity. Depending on what these regulations entail, I don't know if they could possibly prevent an incident like this from happening. I think that it would have to be quite detailed to get to that level, but it's definitely a positive thing.

Ms. Helena Jaczek: Just to reiterate my colleague's question, if the RFP had said something like 40 milli-

grams per millilitre, there would have been no confusion, in your opinion.

Ms. Laura Savatter: No question.

Ms. Helena Jaczek: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. The official opposition? Any further questions? Yes?

Mrs. Amrit Mangat: Thank you, Chair. Thank you, Ms. Savatter, for your presentation. In your presentation, you said that you were in conversation with an OCP pharmacy inspector who—on page 9—you said “confirmed her intention of attending for an opening inspection before May 30, 2012.” Was that inspection conducted?

Ms. Laura Savatter: Yes.

Mrs. Amrit Mangat: Can you share with us what was discussed during that inspection? Were you a part of that inspection?

Ms. Laura Savatter: Yes.

Mrs. Amrit Mangat: Okay. What was discussed during that inspection?

Ms. Laura Savatter: I don't recall the specifics, but it was mainly related to some of the products that would be dispensed at that location. Typically, what they do in an opening inspection is they take a look at your computer software; the drug references that the pharmacy has made available; the procedures in place to ensure no access from the public; the procedures in place to ensure safe tracking and storage of controlled substances and narcotics; refrigeration and temperature control—those types of things.

Mrs. Amrit Mangat: Have you spoken with the college inspectors since the issue arose?

Ms. Laura Savatter: I'm sorry, can you repeat that, please?

Mrs. Amrit Mangat: Have you spoken with the college inspectors since this issue arose?

Ms. Laura Savatter: I have, but not with regard to this.

Mrs. Amrit Mangat: Okay. What have you spoken with them about?

Ms. Laura Savatter: Well, there happened to be an inspection in Hamilton on a day when I was working, and nobody else was around. So it wasn't really into the Mississauga facility, but it happened to be the same inspector, yes.

Mrs. Amrit Mangat: Has anyone from your facility spoken to them?

Ms. Laura Savatter: I believe so.

Mrs. Amrit Mangat: Thank you.

The Chair (Mr. Ernie Hardeman): No further questions?

Thank you very much for your presentation—much appreciated. We look forward to digesting your well-prepared report. Thank you very much.

Ms. Laura Savatter: Thank you.

The Chair (Mr. Ernie Hardeman): That concludes our delegations today, so we will go in camera to discuss about future direction for the committee.

The committee continued in closed session at 1628.

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Mardi 4 juin 2013

Standing Committee on Social Policy

Oversight of pharmaceutical
companies

Comité permanent de la politique sociale

La surveillance, le contrôle et la
réglementation des entreprises
pharmaceutiques



Chair: Ernie Hardeman
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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Tuesday 4 June 2013

Mardi 4 juin 2013

*The committee met at 1614 in committee room 1.*OVERSIGHT OF PHARMACEUTICAL
COMPANIES

The Chair (Mr. Ernie Hardeman): The orders of the day have completed, so we will call the meeting of the Standing Committee on Social Policy to order. It's the June 4 meeting. We're here on a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

BAXTER CORP. CANADA

The Chair (Mr. Ernie Hardeman): We have with us a delegation from Baxter Corp. Canada and they're already at the table. Before we start the meeting, we're doing this all under sworn testimony, so we will ask each one to swear an oath or affirm an oath. The Clerk will do that. We'll do all the people at the table and that way anyone can speak as we proceed with the process.

The Clerk of the Committee (Mr. William Short): I'll just start from my left to right. So it's Ms. Bentley?

Ms. Carol Bentley: Yes.

The Clerk of the Committee (Mr. William Short): Did you want to be affirmed or swear an oath?

Ms. Carol Bentley: Affirmed, please.

The Clerk of the Committee (Mr. William Short): If you could just raise your right hand, please. Ms. Bentley, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Carol Bentley: I will.

The Clerk of the Committee (Mr. William Short): Thank you. It's Ms. Miao?

Ms. Anne Miao: Yes.

The Clerk of the Committee (Mr. William Short): Did you want to swear an oath or be affirmed?

Ms. Anne Miao: Affirmed, please.

The Clerk of the Committee (Mr. William Short): If you could just raise your right hand, please. Ms. Miao, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Anne Miao: I do.

The Clerk of the Committee (Mr. William Short): Thank you. And Mr. Oliver?

Mr. Mike Oliver: Affirmed, please.

The Clerk of the Committee (Mr. William Short): Okay. If you could raise your right hand. Mr. Oliver, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Mike Oliver: I do.

The Clerk of the Committee (Mr. William Short): Thank you. And Mr. Lynch, same thing?

Mr. Phil Lynch: Yes.

The Clerk of the Committee (Mr. William Short): Do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Mr. Phil Lynch: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you all very much. While we went through that, we now have almost a full committee, so we're prepared to start. We will give you 20 minutes to make a presentation to the committee. Then, at the end of the 20 minutes, we will have 20 minutes from each caucus to ask questions or make statements to your presentation. The process will start with the government side when you're through with your 20 minutes. With that, the floor is yours. Again, thank you for being here.

Mr. Mike Oliver: Good afternoon, committee. My name is Mike Oliver. I'm the general manager of Baxter Corp. Today I'm joined by Anne Miao, our director of pharmacy for Baxter Corp., to my right; to my left, Phil Lynch, director of quality for Baxter Corp; to my far right, Carol Bentley, regional director of sales at Baxter Corp.

First, we want to acknowledge the very challenging circumstances that have given rise to the committee's review of the matters at hand. Our thoughts are with the affected patients and their families. We also applaud the efforts and leadership of hospitals and pharmacy teams who have been working tirelessly to support patients. We also thank you for the opportunity to provide to the committee an overview of Baxter and its long-standing partnership with Canadian health care.

As the Canadian subsidiary of Baxter International, Baxter Corp. provides life-saving and life-sustaining

therapies for patients with hemophilia, immune disorders, infectious diseases, kidney disease, trauma and other acute and chronic medical conditions.

Part of Baxter's diversified scope of therapies for patients also includes a drug delivery platform for intravenous molecules. These include intravenous-based solutions and administration sets, premixed drugs and drug reconstitution systems, IV nutrition products, infusion pumps and inhalation anesthetics.

As a global leader in ready-to-administer medication, Baxter also provides intravenous admixing services to hospitals' customers in nine countries around the world, including Canada. These are services that we'll focus on today, which Baxter delivers through Baxter centralized intravenous admixture pharmacy services, otherwise known as CIVA.

In a moment, I will provide some history about why the CIVA arm of Baxter's operation was created. IV admixing is and remains a critical service that is essential to hospital practice and patient care. First, let's focus on IV admixing and why it is a service that has been outsourced to Baxter's CIVA facility.

IV admixing has changed over the years. For example, it was initially done by nurses at the bedside for individual patient dosing of pharmaceuticals. Changes in pharmacy practice recommended by bodies such as the American society of hospital pharmacists and the Canadian Society of Hospital Pharmacists created a movement to centralize preparation of IV admixtures by pharmacists in hospital pharmacies. This created a very heavy workload for hospital pharmacies, many of which lack the appropriate technical infrastructure, personnel, time and facility of space to assume the responsibilities to handle the biohazard risks associated with and posed by oncology drugs.

To provide an alternative solution for hospital pharmacies, Baxter partnered with hospitals enabling them to outsource admixing activities. This helped to relieve the pressure on operations, freeing hospital pharmacies to focus on direct patient care and clinical activities while ensuring patient safety, quality and supply. CIVA has been providing admixing services for Canadian hospitals for 27 years.

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I would now like to take a few minutes and have Anne Miao, our director of pharmacy, provide you with some context regarding where CIVA has started and how and why it has evolved to where it is today.

Anne?

Ms. Anne Miao: Thank you. Good afternoon. My name is Anne Miao. I'm the director of pharmacy at Baxter Corp. Part of my responsibilities includes the CIVA admixing centre. I have been in my current role for two and a half years, and prior to that, I had been practising in hospital pharmacy for over 13 years. Part of my experience in hospital pharmacy included implementation of a unit dose distribution system in hospitals. I am currently a licensed pharmacist with the Ontario College of Pharmacists, category A.

With an aim to help to improve the efficiency of medication preparation, in 1986, Baxter entered into a partnership with one of the Toronto teaching hospitals to operate an admixing centre on hospital premises. The hospital partnered with Baxter to build a clean room, where the admixing activity safely took place.

Initially, all the doses were patient-specific. However, over time, it was mutually agreed upon that, to become more efficient and effective, hospitals would be better served by CIVA if they adopted a system of batched admixtures.

Admixing is not specific to individual patients. Rather, non-patient-specific batches are ordered by the hospital to meet the hospital pharmacy's short-term needs. Appropriate processes were established to permit this to be done safely, with a focus on high-quality standards.

In 2005, Baxter opened a dedicated admixing CIVA facility in Mississauga to service an expanding customer base. The opening of a stand-alone facility was driven by a number of factors, including space constraints, operational dependencies and ensuring continuity of supply.

Today, CIVA Pharmacy Services provides an admixing service, customized and just-in-time, in accordance with the specific needs of the hospital. CIVA aseptically admixes a range of commercially available medications for just over 100 hospitals across Canada. Operating 365 days a year, CIVA provides multiple therapeutic categories, including oncology, anti-infectives, analgesics, nutrition, critical care and cardiology. Every year, CIVA develops between 20 to 40 new admixing codes to better service their pharmacy customers. The development of these codes is a direct result of specific customer requests, and they were developed in consultation with our hospital pharmacists.

CIVA also has an extensive database of drug stability stemming from internal Baxter stability studies, third-party stability studies and recognized literature, as well as the ability to customize labels to meet various industry labelling requirements—for example, Cancer Care Ontario and ISMP.

My colleague Phil Lynch would now provide an overall around our quality procedures and policies.

Mr. Phil Lynch: Good afternoon. My name is Phil Lynch and I'm the director of quality for Baxter Corp. Canada.

At Baxter, we have an uncompromising commitment to the quality and safety of the therapies and services we deliver to clinicians and patients. CIVA is licensed by Health Canada's Office of Controlled Substances for the sale and distribution of narcotics and controlled substances, and is audited by them to ensure adequate controls are in place.

Pharmacists who oversee operations are licensed by the Ontario College of Pharmacists. Each admixture produced at Baxter CIVA Pharmacy Services undergoes rigorous quality processes to ensure aseptic technique, accuracy and applicable good manufacturing practices, or GMP, requirements are followed.

The admixing service is operated under the direction of licensed pharmacists and certified technicians and a quality assurance team that ensures safe and precise processes. We reconstitute medications per the product monograph provided by the pharmaceutical manufacturer. Further, we track, package and label all admixed medications to ensure identification and full traceability.

As part of our commitment to ensure safety and quality, CIVA relies on stringent internal corporate protocols, voluntary standards and best practices Baxter has derived globally from the company's experience with regulatory requirements established in other countries. The CIVA facility adheres to Baxter's global internal quality processes and applicable elements of GMP issued by Health Canada. These systems are regularly assessed through robust audits by Baxter's global compliance group and are continually improved to ensure safety, identity, accuracy, quality and traceability of the service provided.

The CIVA facility has a classified clean room consisting of standards that meet the ISO, so the International Organization for Standardization or ISO 7 requirements, and is equipped with primary engineering controls including Laminar airflow hoods and biosafety cabinets meeting ISO 5 standards. With these in place, CIVA's processes and procedures are designed to meet or exceed the applicable sections of GMP, ISO 14644, and applicable sections of the pharmacy practice guidelines, including United States Pharmacopeia chapter 797.

Mr. Mike Oliver: Thank you, Phil.

You may get some sense as to why hospitals have chosen to outsource admixing services: to achieve a high degree of patient safety and to ensure confidence in the quality of the services being provided. In our view, outsourcing is not done primarily for financial reasons but as a result of the complexity of providing these services in an efficient and effective way. This underscores the criticality of ensuring a strong partnership between Baxter and its customers.

Baxter works hand in hand with each new hospital customer to determine their specific admixing requirements. As a part of the up front needs analysis, Baxter works with each customer to analyze their drug utilization data, identify which drugs could be provided in a batch and develop specific service codes. Once each unique service code has been created, the Baxter CIVA team works with the customer to determine order frequency, minimum order quantities, delivery days and special handling and administrative requirements, including labelling and alerts. A service agreement is drawn up, including a statement of work which outlines responsibilities and accountabilities for both Baxter and the customer. Service codes are not a product. Understanding a service code requires knowledge of how the code was developed and how it will be used clinically.

Baxter appreciates the opportunity to appear here before the committee today. We have highlighted the Baxter-hospital customer partnership and how this

relationship is critical to ensuring that the right treatment is provided to the right patient at the right time.

In closing, in addition to recent regulatory changes introduced by the provincial Ministry of Health and Long-Term Care and the Ontario College of Pharmacists, Baxter would also welcome national standards and guidelines and federal oversight to harmonize admixing standards across the provinces and nationally affirm patient safety.

In addition, as the health system and patient needs evolve, Baxter is committed to partnering with key stakeholders to develop standards that drive patient safety and high-quality outcomes across all levels of health care delivery, including the appropriate procurement process.

We would be happy to answer any questions you have at this time.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation, and we will now start the 20-minute rotation. Mrs. Mangat.

Mrs. Amrit Mangat: Thank you, Mr. Oliver, for your presentation, and welcome to Queen's Park.

Mr. Mike Oliver: Thank you.

Mrs. Amrit Mangat: My question is, for how long has your company been providing these medications through Medbuy?

Ms. Carol Bentley: Hi. I'm Carol, and I can answer that question for you. Baxter and Medbuy had a contractual relationship from November 2008 through to September 2011. As we approached September 2011, that contract was extended for three months so that Medbuy could complete their RFP process.

Mrs. Amrit Mangat: I'm sure that there has been a great deal of discussion about the labelling of these medications. Can you share with committee members how labelling by your company was different, if it was different, from Marchese, to identify concentration?

Ms. Carol Bentley: I think I'm going to ask Anne to talk about labelling.

1630

Ms. Anne Miao: So thank you for the question. I can only speak from our labelling. I have not seen the Marchese label. I am just passing around, circulating, a sample label of our cyclophosphamide codes, as well as our gemcitabine codes. As you can see on the label, we have both the concentration as well as instructions for administration.

The Chair (Mr. Ernie Hardeman): For the rest of the committee, we'll get a copy made of the page that you have there so they can all—

Mrs. Amrit Mangat: So in order to ensure that what happened doesn't happen again, what measures do you think should be taken?

Ms. Anne Miao: With the permission of the panel, I think it may be helpful if I walk you through a process of how Baxter CIVA prepares a gemcitabine code for a customer. Would that be all right?

Mrs. Amrit Mangat: Chair, is it okay if she walks us through the process?

The Chair (Mr. Ernie Hardeman): Yes, that'd be fine.

Ms. Anne Miao: I'm just going to refer to my notes to make sure that I have everything correct.

When we admix any codes for hospital customers, first and foremost, we work and collaborate with our hospital pharmacists to understand exactly what their needs are and how they will be administering the medication. I'm using an example of gemcitabine four grams in this process. Let's start at the point that gemcitabine comes in two-gram vials, and each vial requires 50 millilitres of normal saline to reconstitute. In working with Baxter's hospital customers, we have determined that it would be ideal if we can put two vials of two grams together to make a four-gram code because it would be easiest for the hospital pharmacists to draw down from the bags.

Originally, when we were discussing the challenges that the hospital pharmacists had, they were indicating that the most critical pinch point for them was the reconstitution process because it takes them about four hours to reconstitute. Because we understand that we cannot standardize oncology dosing, we can derive a process whereby we mitigate the reconstitution portion of the process for them.

At the CIVA centre, we would withdraw 50 millilitres of normal saline and administer it into each two-gram vial to reconstitute. Once it's in solution format, we withdraw the entire contents of each vial and inject it into an empty non-DHB bag. The rationale for that is because once we reconstitute the vials, the vials are not tamper-proof anymore, and we did not feel that it was safe to transport the reconstituted vials as such back to the hospital. So we proposed that we inject it in a closed-system empty bag whereby we can then transport it back to the hospital. The hospital pharmacists would then wait to receive a prescription from an oncologist with the prescribed dose for each individual patient. They will look on our label and use the concentration listed there to calculate the exact dose required as per the prescription from the oncologist.

Usually, the way each dose is calculated is based on height and weight and using a formulation to determine the body surface area. Based on the calculation from the body surface area, each dose would be determined. They would then withdraw the appropriate amount from the four-gram bag. Then they would further dilute it in a vehicle, be it saline or dextrose, depending on the prescription. Then they would put individual patient labels on it and then have it double-checked and sent up to the floor for administration.

So I hope that sort of helps illustrate the processes.

The Chair (Mr. Ernie Hardeman): Okay. Thank you very much.

Mrs. Amrit Mangat: Thank you.

The Chair (Mr. Ernie Hardeman): Ms. Jaczek?

Ms. Helena Jaczek: Thank you for that very clear description of the process.

You were quite clear in your own mind then, when you were the recipient of the Medbuy contract, that the admixed compound was not going to be used for a single patient? You mentioned that and it's clear from your description that you fully understood it was not going to be the whole bag for one patient. Is that correct?

Ms. Anne Miao: Yes, that's correct.

Ms. Helena Jaczek: Were you clear, from your Medbuy contract, that a specific concentration was required to be admixed to a specific concentration?

Ms. Anne Miao: If I may just point to the 10 steps. We developed that admixture code with the customers and, as a result, we know that what they really wanted was to have us do the reconstitution as per product monograph. So the final concentration of the reconstituted solution, as per product monograph, is what they required and that's how we prepared the admixture for them.

Ms. Helena Jaczek: So when you received the contract from Medbuy, which, as we have seen at least on the most recent RFP process, when it came to gemcitabine, four grams per 100 millilitres, you felt that you needed to go to the hospital pharmacist and have a further clarification. Is that correct? Or was the RFP clear to you, that you would know what to do?

Ms. Carol Bentley: Maybe I can help with this. The contract that Baxter and Medbuy had between 2008 and 2011 formalized a relationship that had been going on before that for quite some time between Baxter and Medbuy's member hospitals. In the way we work with hospitals, we have a number of sales representatives who actually work with the hospitals to develop whatever admix codes they require. So Medbuy, in conjunction with their members—and this is back in 2006-07—basically asked their committee about formalizing a contract with Baxter for admix services, and that was done in 2008.

Ms. Helena Jaczek: So your relationship kind of predated, with the hospitals—

Mr. Mike Oliver: Yes.

Ms. Carol Bentley: It did, yes.

Ms. Helena Jaczek: When you looked at the RFP that you bid on, I guess early 2012, when you saw the requirements in the schedule from Medbuy, how maybe—again, to the pharmacist, how would you have interpreted that?

Ms. Anne Miao: Just for clarity, the RFP was out in 2011. We looked at the listing, as they have indicated in the RFP, and we were required to submit label samples for each code. As you can see, our label samples actually include the displaced volume of the drug. So it actually says 105.26 millilitres for gemcitabine for four grams.

Ms. Helena Jaczek: Did you get any feedback on whether your labels were acceptable?

Ms. Carol Bentley: No. We were the incumbent at the time. Do you mean, did we get feedback in the debrief from the RFP?

Ms. Helena Jaczek: Yes, exactly.

Ms. Carol Bentley: Yes. When we were not awarded the business—we were notified in December 2011 that

we were not getting the business again for another term—we requested a debrief meeting, which you're allowed to do in the procurement rules. In the debrief meeting, they did mention, as they marked our answers to criteria, that one of the issues was labelling.

Ms. Helena Jaczek: It was one of the issues?

Ms. Carol Bentley: It was called out, yes, in terms of—however, there was no specificity in terms of—

Ms. Helena Jaczek: Of why?

Ms. Carol Bentley: Of why.

Ms. Helena Jaczek: Okay. Perhaps we'll turn to this grey zone that we've heard about. With its long experience in this particular line of work, was Baxter aware about the lack of regulation specifically related to admixing?

Mr. Phil Lynch: Yes, we were aware of that. We have been partnering with Health Canada in all of our businesses for a number of years, so we were aware that we were in a grey zone.

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Ms. Helena Jaczek: We heard yesterday from Marchese that they made a tremendous effort to try to find out how they perhaps could be regulated. Was that a conversation that Baxter had also had with Health Canada or the College of Pharmacists?

Mr. Phil Lynch: During my tenure here at Baxter, I have had a conversation—or two conversations—with Health Canada regarding CIVA.

Ms. Helena Jaczek: How many years ago would that have—

Mr. Phil Lynch: Within the last two years.

Ms. Helena Jaczek: In the last two years.

Our government has introduced a number of measures, as you're no doubt aware, and Health Canada is involved. Do you feel that it is a step forward that we are attempting to put more oversight into the admixing business?

Mr. Mike Oliver: I think we would agree that anything that ultimately has patient safety as the cornerstone of any regulation, whether that is provincial or whether that is federal—we very much would welcome that.

Ms. Helena Jaczek: Baxter has a number of different divisions. Perhaps you could explain to us your various businesses and what type of oversight there is existing in some of these other areas that were involved.

Mr. Mike Oliver: Sure. I'll talk a little bit about our organization, and then I'll ask Phil, maybe, to talk about the quality standards that exist.

Baxter is divided into two global businesses: One is biosciences, and one is medical products. Within medical products, you have a number of what we call internal franchises. With those franchises, there would be IV therapy, fluid systems, and then we have a big renal portfolio.

In Canada, we're one of the few medical device manufacturers that still manufacture in Alliston, Ontario. We provide and manufacture on an annual basis about 67 million IV bags or renal bags, 97% of which are provided for Canadians.

We have a very rigorous quality system in place, and I'll ask Phil to make some comments on the manufacturing processes associated with that. The plants that sit outside of Canada would all be subject to a similar level of internal and external scrutiny related to manufacturing practices. But specific to the Alliston facility—Phil?

Mr. Phil Lynch: Thanks, Mike. Our Alliston facility falls under GMP, so it is under Health Canada licence, as is our general office. That would cover off all of our medical devices, as well as drug products that we import from various facilities in Baxter.

We are also covered by the medical device regulations, as Mike has noted, so SOR/98-2. We have a technical service centre where we would repair some of our medical devices, as well as a third party warehouse facility where we perform release of our products to the Canadian market.

Mr. Mike Oliver: I would just add, in addition to Phil's comments, there are a number of devices and instruments that require pre-approval from Health Canada. In order for you to be able to sell the product in Canada, it has to be licensed under Health Canada. It's a formal submission process, and they review those technologies, typically in a reasonable time—and then launch them in the marketplace. But you cannot sell them in Canada until Health Canada has officially approved them.

Ms. Helena Jaczek: We'll reserve our time, Mr. Chair.

The Chair (Mr. Ernie Hardeman): To the official opposition. Mrs. Elliott.

Mrs. Christine Elliott: Thank you very much for appearing before the committee today. We really appreciate it.

If I could just go back to 2008, when you first started negotiating the contracts with Medbuy—and I believe the first was on behalf of the London Health Sciences Centre. Is that correct? Was London the first one?

Ms. Carol Bentley: London Health Sciences was one of the members that belonged to Medbuy, yes.

Mrs. Christine Elliott: Okay. But that was done before Windsor or before Lakeridge, so that was—

Ms. Carol Bentley: I'm not exactly sure when it was done. I wasn't with Baxter then.

Mrs. Christine Elliott: Oh, okay. Well, in any event, in the first instance, you've indicated that the contract was just the culmination of your discussions that happened before that. Could you just let us know exactly—step us through the process of what would happen. You would have received the RFP, and then you would have gone and had discussions with them. Could you please tell us a little bit about that background?

Ms. Carol Bentley: The CIVA business has been here for 27 years, and it's basically us meeting with pharmacists—who are one of the people who we call in most of the time—and discussing that we did have this service, and developing products that met their needs. So this evolved over many, many, many years with many different hospitals in the marketplace.

The list of codes that we developed might have been hospital specific, or if one hospital was using them and that was of value to another hospital, then we would have that discussion with the pharmacist as well. Medbuy's contract with us in 2008 basically just formalized a process that had already started and predated that in the years before with their member hospitals.

Mrs. Christine Elliott: So as far as Baxter was concerned, there was no question about what product was going to be produced and what it was going to be used for.

Ms. Carol Bentley: That's right, because we were involved with the hospital pharmacist every step of the way in terms of determining what the requirements are and how we could meet those requirements.

Mrs. Christine Elliott: And would your contract have been that specific to reflect that, the specific needs of what was to be produced?

Ms. Carol Bentley: The contract reflected the codes that were in scope of the contract for all the members that belonged to Medbuy, but we had that basic understanding of the history of how those codes got produced and what they were. We had that understanding as we entered into that contract, yes.

Mrs. Christine Elliott: And the first contract, was that the same contract that you used in further discussions? Did it form the template for all of your other admixing contracts with the other health corporations or hospitals that were involved?

Ms. Carol Bentley: Contracting has evolved over the last couple of years—

Mrs. Christine Elliott: I'm specifically speaking about the contracts involving London, Windsor and Lakeridge.

Ms. Carol Bentley: Okay. London, Windsor and Lakeridge were all part of the Medbuy contract, and we worked with those member hospitals within the scope of that contract that we had from 2008 to 2011.

Mrs. Christine Elliott: Would you be able to provide us with a copy of that contract?

Ms. Carol Bentley: I don't see why not.

Mrs. Christine Elliott: I think it's important because there seems to be a discrepancy in terms of the specificity of the contract that was between Medbuy and Marchese. I think it's important for us to understand the differences, if any, between the two contracts because that seems to be the basis of some discussion, so that would be very helpful if you could provide us with a copy of that.

Mr. Mike Oliver: It's important, too, that prior to the admixing contract with Medbuy, Baxter would have already had a number of already pre-existing contracts with Medbuy. I think this was—Carol can correct me if I am mistaken—the first time Medbuy had gone into the admixing space. Typically they would be procuring a lot of our other devices on multi-year contracts. Likewise, there are other GPOs in the country that do the same thing, some based in Ontario.

Mrs. Christine Elliott: You were dealing with the hospital pharmacists. What involvement did you have with Medbuy specifically?

Ms. Carol Bentley: In the period that we had the contract we formalized the contract and the codes there. But also, during that time, if their member hospitals required additional admix codes for additional items, we would work with the hospitals to develop those codes, as Anne described, and then we would add those codes to the contract.

Mrs. Christine Elliott: Thank you.

The Chair (Mr. Ernie Hardeman): Mr. Yurek?

Mr. Jeff Yurek: How was your relationship with Medbuy over the years? Were they easy to work with? Did they have a process outlined so if there was a problem with your product they could follow up with you, or their member hospitals could follow the process and bring their questions or concerns to Baxter?

Ms. Carol Bentley: Yes. We have a good working relationship with Medbuy. And, yes, if there were issues as they related to products or anything else, they have a procurement team that would contact the supplier and articulate what those concerns are.

Mr. Jeff Yurek: And that was from Medbuy, the procurement team?

Ms. Carol Bentley: Yes, Medbuy has a procurement team.

Mr. Jeff Yurek: Now, did you know of any process they hadn't placed in the hospital setting or pharmacy setting where they could start a process to say, "I'm not happy with this product"? Do you know of any?

Ms. Anne Miao: Yes. Typically if there is a concern with any products directly received in the hospital pharmacy they would contact the CIVA centre. There's a coordinator at the CIVA centre which will take down their concern and address it appropriately with the entire CIVA team. As well, each hospital has a sales representative that is liaised with that hospital. They may reach out to the sales team, as well, directly, who in turn will bring it in to the CIVA centre.

Mr. Phil Lynch: I might just add to that: That would flow into our quality system through the complaints and adverse event reporting systems as well.

Mr. Jeff Yurek: Now, with regards to the RFP that was released in 2011, what are your thoughts on the RFP? Was it clear? Was it definitely laying out what exactly the winner of the RFP would have to provide?

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Ms. Carol Bentley: Since we had been the incumbent before, we were very clear in terms of what the obligations would be in the next contract period.

Mr. Jeff Yurek: You were clear.

Ms. Carol Bentley: Yes.

Mr. Jeff Yurek: But was the contract clear that they were asking in the RFP—was that clear? You did the work beforehand, so obviously you knew what was going forward, but was the document that Medbuy provided to you clear—

Ms. Carol Bentley: Yes, it was clear.

Mr. Jeff Yurek: —on understanding?

Ms. Carol Bentley: Yes.

Mr. Jeff Yurek: Did you help create the RFP contract with Medbuy?

Ms. Carol Bentley: They asked us in the RFP process—so that precedes the RFP process—for a list of items that their member hospitals were purchasing from us, and we provided that information to Medbuy.

Mr. Jeff Yurek: Just with regard to oversight, you didn't have a pharmacist on site, so the college of pharmacy had nothing to do with your business.

Ms. Anne Miao: We do have registered and licensed pharmacists on site, more than one.

Mr. Jeff Yurek: At CIVA?

Ms. Anne Miao: Yes, at CIVA.

Mr. Jeff Yurek: Okay. I didn't realize that. Did you have any dealings with the college of pharmacy at all?

Ms. Anne Miao: Other than through the normal licensing channel for the pharmacists?

Mr. Jeff Yurek: Yes.

Ms. Anne Miao: No.

Mr. Jeff Yurek: And Health Canada: I might have missed that. What role did Health Canada play with CIVA?

Mr. Phil Lynch: Over the last couple of years I've had conversations with the Ontario inspectorate, which reports up through Ottawa, around how we perform our activities at CIVA.

Mr. Jeff Yurek: Did they have inspections and such of the facility?

Mr. Phil Lynch: No. Health Canada, through the Office of Controlled Substances, would audit our facility because we're licensed to distribute narcotics. That was the only auditing.

Mr. Jeff Yurek: Did you ever think of working with the OCP and Health Canada to develop oversight or did you not think it was necessary?

Mr. Phil Lynch: We had had some conversations around that, but they were informal.

Mr. Jeff Yurek: Just my last question for now: Did you batch weekly, daily for the hospitals? How did you prepare the—in what quantities did you prepare the product or how often did you?

Ms. Anne Miao: It varies between the hospitals. As we mentioned all through, we work very closely with the hospitals to understand the quantity and the codes that are required. We do admix on a daily basis. Whether we ship to hospitals on a daily basis depends on their ordering schedule. We work with them, ensuring that there's appropriate inventory turnover.

Mr. Jeff Yurek: Jane, do you have any—

The Chair (Mr. Ernie Hardeman): Ms. McKenna?

Mrs. Jane McKenna: Do you know who your competitors are?

Mr. Mike Oliver: In Canada, our primary competitor for the Medbuy contract was Marchese, which I think at the time we had some competitive information around. I wouldn't necessarily term it as a competitor, but we view the ability to improve patient safety and efficiency as

taking the volume of that service out of hospitals. Doing it in our facility, with the standards that we have, at the volume that we do it, adds tremendous efficiencies, and in some cases cost efficiencies as well.

Mrs. Jane McKenna: Just for myself, if you knew that was your competitor—when they came in here, Ms. Zaffiro said that Medbuy didn't put an RFP out because they didn't realize there was anyone to compete with you at all. Ms. Zaffiro came forward to say that she wanted to bid on this RFP.

When you asked what was the reason that you didn't get the project and they said that it was the label, are you not able to see that, to actually see what the reason was? Would you not want to know what the reason was? Because to be in business 27 years is a long time, and to have someone say, "You've got a label problem," and then you don't know exactly what the label problem is—

Ms. Carol Bentley: Yes. Maybe I can clarify a couple of things. In March 2011, Medbuy issued an ACAN. An ACAN is a statement to the marketplace saying that they would like to enter into a contract again with us for CIVA services. Basically, that process tells the marketplace, and if there are any challengers, then Medbuy is obligated, through the procurement process, to issue an RFP. That's what she was referring to.

At that time, we found out that there were challengers to the ACAN process and therefore they moved to the next step, which is an RFP. I think it was at that time that we formally found out that there were other entities in Canada that were interested in this space as well. So that's the answer to your first question.

The second part is, in the RFP document, it clearly outlines an RFP process. Within Medbuy's document, the process identified that the proponent who was not getting the business could go to a debrief meeting, which we did. We requested the debrief and we went in in January. At that time, we asked what were the—it was all done on scoring, so there were criteria that were developed by the committee, and then it was scored by the committee. There were areas where our scores were less than Marchese's. One of those things was labelling. There were other things, but labelling was one of the things that was called out, and bar-coding in particular.

Mrs. Jane McKenna: When you got that—and I'm assuming you sat there through that process to see what the reason was—you were okay walking away with that? You felt that there was a legitimate reason why you didn't get it?

Ms. Carol Bentley: Well, we were very disappointed that we didn't get it. Unfortunately, in the process that was outlined in the RFP, proponents were asked to honour the process, and there wasn't a way for us to dispute it.

Mrs. Jane McKenna: Okay. That's it for me. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. To the third party: Ms. Gélinas.

M^{me} France Gélinas: I'll pick up exactly where she left off. You had been supplying those drugs to the

hospitals for years. All of a sudden, Medbuy happens and says, "Oh, we will do a formal contract of a business transaction that was already there." Then in 2011 came the RFP for a business transaction that had already been there for years, that you had continued under a new contract, but basically the work had not changed and everything was fine; you lose that contract and you're told that it's because the label is an issue.

Why wasn't the fact that your labelling was an issue brought forward to you in those 27 years of continuous talking between you, the pharmacies and the hospitals?

Ms. Carol Bentley: I don't know.

M^{me} France Gélinas: All right. We were also told that you lost the contract because of service issues. Do you know what those service issues were?

Ms. Carol Bentley: Yes.

M^{me} France Gélinas: What were they?

Ms. Carol Bentley: In the debriefing—I'll just talk a little bit about the scoring. In the RFP document, it is very clear to the proponents in terms of how your proposal will be scored: 25 points were for financial, 75 points were for other criteria. Those other criteria were pharmaceutical and technical criteria, labelling criteria and what they called business criteria. All of those criteria were developed by Medbuy in conjunction with their pharmacy committee.

When the proposals were sent back to Medbuy, those criteria were rated based on a scoring system that was determined by the committee. It was during those reduced scores that we got that I was led to believe that that contributed to us losing the business. We did ask for a debrief, but the information that was provided was very, very high level in terms of where we lost points in our scoring.

M^{me} France Gélinas: Did they talk to you about cost at all?

Ms. Carol Bentley: No. Never.

M^{me} France Gélinas: Never? Okay, well, I will talk to you about cost. We now know that your proposal for gemcitabine—I always want to pronounce those in French; it makes way more sense to me—for four grams, you came in at \$34 and Marchese came in at \$5.60.

Ms. Carol Bentley: Oh.

M^{me} France Gélinas: Any idea as to why it would cost you \$34 to do something that Marchese can do for \$5.60?

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Ms. Anne Miao: I cannot comment on the processes under Marchese's jurisdiction because I have no visibility to that. What we base our costing on is time-motion studies at our CIVA centre, as well as the cost for the ancillaries.

M^{me} France Gélinas: The cost of \$34 that you submitted, was it significantly different from the cost that you had been charging the hospitals before?

Ms. Anne Miao: No, it wasn't.

M^{me} France Gélinas: It was the same price that you had been charging since you had been doing admixture.

How often would you increase your prices for the admixture?

Ms. Anne Miao: It varies. As you know, sometimes the ancillary costs increase, and if we change certain processes—for example, automate certain processes—we can have more efficiency in the cost. So we can actually decrease prices as well.

M^{me} France Gélinas: When would you pass on those savings? How is that done? When do those changes in prices take place?

Ms. Carol Bentley: Within the contract, usually there are ongoing business meetings that we have with our business partners. With Medbuy, it would be quarterly or semi-annually, and we would discuss pricing or pricing changes at that time. Perhaps they would happen once a year. I wasn't here so I don't exactly know what happened in the previous contract.

M^{me} France Gélinas: When Medbuy came in with the RFP—we're now in 2011. They go to you, and in the RFI, they actually ask you to provide a list of products. You're the one who gives Medbuy, "Here's all our codes; here's everything that we're presently providing as a subcontractor to your member hospital."

Ms. Carol Bentley: Right.

M^{me} France Gélinas: When they put that back out as an RFP, did you pretty well recognize the stuff that you had already submitted to them?

Ms. Carol Bentley: Yes.

M^{me} France Gélinas: Okay. So they took your information and put it out there as an RFP. You knew exactly what it was because you had been doing the work. Had anything changed to make it clearer, or was it your stuff that got back out?

Ms. Carol Bentley: No, it was pretty much what we had been providing to the hospitals.

M^{me} France Gélinas: Okay. So when you responded to the RFP, you knew exactly what was required of you. You know that what was required of you was a concentration-specific admix.

Ms. Anne Miao: If I may take that, we know exactly the concentration required for each admixing code, and we also know which ones were dose specific and dose non-specific.

M^{me} France Gélinas: And you know that because?

Ms. Anne Miao: We work with our customers to develop the codes.

M^{me} France Gélinas: Okay. So I'm trying to look at where the knowledge transfer happened. The knowledge transfer did not happen through the work of Medbuy; it happened through the work that you had done directly with the hospital receiving your products.

So here again—I'm trying to understand the processes as good as I can—what value add to clinical pharmacy does Medbuy bring?

Ms. Anne Miao: I believe Medbuy's value is as a procurement expert.

Ms. Carol Bentley: That is their mandate.

M^{me} France Gélinas: They have very good lawyers who know how to negotiate numbers really well and write contracts really well?

Mr. Mike Oliver: I think the primary role of GPOs in this country is to consolidate volume. If you look at Medbuy in this situation—and it's not limited to this situation, and there are others in this country—they take the volume of not one hospital, but 10, 20, 30 or 100, consolidate it, and in doing so hope to achieve efficiencies in purchase price.

M^{me} France Gélinas: Okay. Why can't hospitals get together and do that themselves?

Mr. Mike Oliver: Some of them do.

M^{me} France Gélinas: Some of them do?

Mr. Mike Oliver: I've been around this business a long time. There are groups of hospitals that do the same. There are some in this province that have come together and formed alliances in various parts of the country.

There are only two national GPOs. Medbuy is one of them; HealthPRO is the other. They are the only two that I am aware of that do national procurement, and hospitals belong to one or the other.

M^{me} France Gélinas: I don't know if you read the testimony, but I have really brought a focus to every time there is a hand-off, there is a risk of error in health care. By Medbuy existing, they've just increased the hand-off three times. But because of your previous involvement, you basically bypassed this by going right back to the pharmacy, to the hospital, to make sure that the products you deliver are what are required. But was that required of you, through Medbuy, to do that?

Ms. Carol Bentley: There is an expectation from Medbuy to service their hospitals and to service and meet the requirements, so I think that was, yes, their expectation.

M^{me} France Gélinas: So the expectation is that once you have the contract, you go back to the actual member hospital to see exactly what it is that you're to deliver?

Ms. Carol Bentley: In this particular instance, with this product, it's very important that you do that, yes.

M^{me} France Gélinas: Okay.

Ms. Anne Miao: If I may expand on Carol's response, it has always been Baxter's focus to work with health care professionals. Our focus is for patient quality of care and, hence, it is of our own volition, since the 27 years, to work collaboratively with health care professionals in the hospitals.

M^{me} France Gélinas: Okay. But I'm trying to pinpoint, as in—so you've been doing this, without any issue that made the front page of the paper, for what would have been 24 years. Medbuy comes around, puts in a contract, something that's already there. Then in 2011, we go out with an RFP for the first time, which you will lose.

Where in this RFP does it say that what you bid on is actually maybe not the final products, that you will have to go back to the hospital to know what final products you are to deliver? I read the thing and I didn't see it, but I'm not a pharmacist.

Ms. Anne Miao: I can't comment on the interactions with Medbuy and the hospital nor with Medbuy and Marchese, because I have no visibility to that. I can only comment, and as we've stated before, that it is Baxter's focus to always work with the hospitals directly.

M^{me} France Gélinas: I guess you've answered: This is your focus. It is not a requirement of Medbuy that you go back.

Ms. Anne Miao: No.

M^{me} France Gélinas: It is because of the way you do business, to ensure quality and everything else that you've done. Okay. That answers my question.

Because, again, I'm not a pharmacist, would there be a great change in the price you would have quoted if you wouldn't have known that this thing had to be concentration-specific; if all you had to do was go from a powder form to a liquid form and not be concentration-specific, and just use a pre-filled bag, mix the thing and put it in a pre-filled bag? Would there have been a difference from your \$34 that you had quoted, had you not known that you had to be concentration-specific?

Ms. Anne Miao: That is not our process. Because this is an oncologic, we take specific process precautions to protect our staff as well as the patient, to ensure accurate dosing. So we would not have looked at that as a process.

M^{me} France Gélinas: Okay. So it was clear to you that this is an oncology product that will be used concentration-specific, based on the patient's body mass and all the rest of it. So it never entered the RFP process that you may have to supply this in a different way.

Ms. Anne Miao: No, and I just want to clarify: We understood that the admixing code was not dose-specific.

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M^{me} France Gélinas: Okay. Would you be able to provide four grams of gemcitabine for \$5.60 in an admixture?

Ms. Anne Miao: I cannot comment on that because we will not be using that process.

M^{me} France Gélinas: Okay. Fair enough. I'll save time for the next round.

The Chair (Mr. Ernie Hardeman): Okay, thank you very much. Ms. Jaczek.

Ms. Helena Jaczek: Sorry to dwell on this concentration issue to such an extent, but the reason we're here is because a number—hundreds of people—received a product that was diluted to an extent that obviously was picked up by the Peterborough hospital and so on. When I look at the RFP, and since we're talking about gemcitabine, we'll just continue to talk about it, I see four grams in 0.9% sodium chloride injection bag, 100 millilitres per bag. To me, that is the same thing as 40 milligrams per millilitre. Would you agree?

Ms. Anne Miao: I would agree.

Ms. Helena Jaczek: When you were responding to this—I know you'd had your historical relationship with hospital pharmacists and you'd been admixing and so on—why didn't you just go with this particular concentration?

Ms. Anne Miao: Because it's not accounting for the displaced volume of the lyophilized powder.

Ms. Helena Jaczek: Do you feel that what you were proposing to do—I don't know if you know, if you continued to have your relationship with hospital pharmacists. They are now doing this themselves; they are mixing themselves. Are they taking account for the displaced volume? How are they doing it?

Ms. Anne Miao: I can't comment on it because I'm not privy to the process they use in the hospital.

Ms. Helena Jaczek: In other words, you wouldn't think that—notwithstanding you wanted to account for the displaced volume, but surely you could have actually produced a product that was 40 milligrams per millilitre?

Ms. Anne Miao: Correct.

Ms. Helena Jaczek: You could have, but since you'd always done it that way, you ended up with 38.

Ms. Anne Miao: We followed the product monograph directions.

Ms. Helena Jaczek: I see. At any point, then, when you were preparing your response to the RFP, was this an issue? Did you call Medbuy and say, "By the way, the product monograph says to do it this way, and it's not going to end up with 40 milligrams per millilitre"? Did that conversation take place?

Ms. Anne Miao: That wasn't part of the RFP request.

Ms. Helena Jaczek: Did you feel you might have wanted to clarify that? Or it just never came up?

Ms. Anne Miao: I believe there was a pharmacy expert panel within Medbuy that was evaluating the whole RFP.

Ms. Helena Jaczek: And then, again, when you were debriefed, other than that there was a labelling issue, there was no specificity: "We were worried about the concentration"?

Ms. Anne Miao: No.

Ms. Helena Jaczek: Okay. As we know, Dr. Jake Thiessen has been appointed by our government to look into the whole sequence of events. Has Dr. Thiessen been in touch with Baxter at all?

Ms. Anne Miao: Yes. Baxter had preliminary communication with Dr. Thiessen and he has a planned visit to our CIVA centre.

Ms. Helena Jaczek: I see. Then, going back to—I think it was Mr. Lynch: You were aware of this grey area of lack of regulation for some two years. Can you tell us a little bit about the safeguards that you have in terms of quality control? Being aware of this, I would assume a large company like Baxter would want to put in some guidelines and various quality control issues. Could you tell us a little bit about that?

Mr. Phil Lynch: Absolutely, and just let me clarify: I've been at Baxter for five years, so I've been aware of the CIVA operation for that time. It's been the last two years that I've personally had conversations with Health Canada.

Baxter, like I said, has partnered with Health Canada on a number of areas in all of our operations within Canada. We've taken the regulatory requirements for

drugs—GMP manufacturing requirements—and applied them to our CIVA centre.

As Mike also spoke to, we have a number of similar operations globally. In many of the countries, they are regulated, so Baxter has incorporated these regulatory requirements as well as a lot of the established best demonstrated practices we have across the industry and put these into corporate quality procedures that govern how Baxter operates these facilities. So these are all implemented within the CIVA centre. They are evaluated by our corporate compliance group on an annual basis to ensure that they are effectively implemented, and we continuously improve them.

The Chair (Mr. Ernie Hardeman): Ms. Jaczek, that concludes your time. Thank you very much.

The opposition: Ms. Elliott.

Mrs. Christine Elliott: If I could just go back to the RFP of 2011 and the contract that subsequently resulted from that, you had been in contact with the pharmacists and you had already supplied the products, so you knew pretty much what was required and it was concentration specific. You did indicate that you thought the RFP was clear. Was that because you already knew what you were going to provide, rather than the wording of the RFP itself?

Ms. Anne Miao: May I take that?

Mrs. Christine Elliott: Yes.

Ms. Anne Miao: I just wanted to clarify again that to a pharmacist, concentration can be represented as the active ingredient over a total volume or over a unit volume. So concentration is concentration. I believe the difference is that we know that gemcitabine four grams was not going to be used as one single dose for a patient. Does that help?

Mrs. Christine Elliott: Yes. I guess what I'm really getting at is: Your knowledge of what was required was based more on your specific knowledge of what the hospital pharmacist wanted, rather than the specific wording of the RFP. Is that correct?

Ms. Anne Miao: Partially correct. As well, if you look at the product monograph dosing for gemcitabine, in order for a four-gram dose to be used as a single-patient dose using a standard five-foot-ten patient, you're looking at a patient over 900 pounds.

Mrs. Christine Elliott: So you knew that you needed to be very specific with this and that it would be used specifically for each patient, depending upon their height and weight.

Ms. Anne Miao: We know that the bag would be drawn down as per patient requirements from the prescription in the hospital.

Mrs. Christine Elliott: Do you recall ever having any specific discussions with Medbuy about that? You discussed it with the hospital pharmacists, but did you have any discussions with Medbuy about the requirements and the usage?

Ms. Anne Miao: No.

Mrs. Christine Elliott: So the contract that was drawn up was drawn up basically by Medbuy for signa-

ture, but you knew yourselves that what needed to be provided wasn't really based on any specific discussions you had with Medbuy.

Ms. Carol Bentley: Right, and Medbuy, don't forget, is in council with a pharmacy committee. Part of their operating procedure is that the pharmacy procurement group work with a panel of pharmacists who are represented by each of their member hospitals. That panel or that committee works very, very closely with Medbuy in the decisions on the contracts and clarity understanding. That's part of their business model.

Mrs. Christine Elliott: Did you have any discussions with the committee in this whole process around the 2011 RFP?

Ms. Carol Bentley: During the formal RFP process, no, we did not have formal discussions with the committee.

Mrs. Christine Elliott: Thank you.

The Chair (Mr. Ernie Hardeman): Mr. Yurek.

Mr. Jeff Yurek: Just a quick question. The College of Pharmacists will now be inspecting Baxter's CIVA. Do you welcome that oversight?

Ms. Anne Miao: Yes, we fully support the college's regulation, and in fact we've received notification from the college inviting us to have input to the standards, working with them.

Mr. Jeff Yurek: Further to that, what are your thoughts—I guess this would be more an opinion question to you—on expanding the college into hospital pharmacies?

Mr. Mike Oliver: I think we would welcome any regulation that will ensure patient safety, whether that is provincial or federal, in whatever centre it's done. We're agnostic of where it's done, whether it's at our facility or in a hospital. Regulations that improve and drive patient safety—we welcome that.

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The Chair (Mr. Ernie Hardeman): You have about one minute left, if you want it.

Mr. Jeff Yurek: No.

The Chair (Mr. Ernie Hardeman): We can come back to you. Ms. Gélinas?

M^{me} France Gélinas: Okay, I'm back at gemcitabine and the stability data. You have a procurement process and a distribution process that allow you to get this admixture to the hospital within the four days that your stability data was telling you was the expiry date on this product.

Ms. Anne Miao: I thought it was longer than four days, but yes.

Ms. Carol Bentley: It's four days, but part of our quality process is understanding what the stability is of the admixed products, and then making sure that delivery and filling orders and so on, and how it's delivered, meet those requirements and within that stability data.

M^{me} France Gélinas: How do you ship things to New Brunswick in a way that they can use this within four days?

Ms. Carol Bentley: Is it four days or 30 days?

Ms. Anne Miao: I can't remember. Is it exactly four days?

M^{me} France Gélinas: That's what your own stability data tells us. We have access to the documents that you have supplied.

Mr. Mike Oliver: We would use the shipping protocol.

Ms. Anne Miao: Oh, sorry—

Mr. Mike Oliver: Yes, go ahead.

Ms. Anne Miao: Sorry, I remember now. When we submitted that stability, we had four days, but since then, we have extended stability based on literature and others that have extended it beyond four days.

M^{me} France Gélinas: Okay, so it was four days, and now it's longer.

Ms. Anne Miao: Right, and if you noticed, a lot of our faraway customers did not order gemcitabine from us.

M^{me} France Gélinas: Okay. Were you surprised to learn of the error when you saw the papers, when you read the news?

Ms. Carol Bentley: Yes, I was surprised.

M^{me} France Gélinas: I'd like to hear the pharmacist.

Ms. Anne Miao: Yes, I was surprised.

M^{me} France Gélinas: What other feeling came to mind besides surprise?

Ms. Anne Miao: I felt really bad for the patients and their families.

M^{me} France Gélinas: Do you feel that this could have been prevented?

Ms. Anne Miao: I believe Dr. Thiessen's report would enlighten us as to the root cause, and that would perhaps help me answer the question.

M^{me} France Gélinas: Do you figure that would have happened if Baxter had continued to provide the drug?

Ms. Anne Miao: I feel that our processes in place are of high standards and quality, that we would have continued the high level of service that we have been supplying our customers.

Mr. Mike Oliver: We don't believe that that would have happened at Baxter.

Mr. Phil Lynch: We feel that our quality processes and redundant operational processes are such that we're proactively able to identify issues and respond to them accordingly.

M^{me} France Gélinas: And this includes going back to the pharmacy of the hospital using your products to see how what you do can be useful to them?

Interjections.

M^{me} France Gélinas: Do you figure that it should be part of the requirement of Medbuy from now on that the quality and redundancy that you have put within your process be extended to everybody else who does the same thing you do?

Ms. Carol Bentley: Yes, I'll answer this one. In the procurement processes for very clinically sensitive and complex products and services, I think there needs to be a deep understanding of how the products are used and of

the business and what is to be provided. I think that including quality elements like that within the procurement processes would be helpful in the future.

M^{me} France Gélinas: Are you worried that hospitals are now doing it in-house?

Ms. Anne Miao: I feel that the Ontario College of Pharmacists has guidelines in place that allow pharmacists to practise, and this is well within their scope of practice.

M^{me} France Gélinas: Except that every pharmacist we've talked to who works in a hospital tells us that they have nothing to do with this; it's the technicians who handle it. But I take it that that goes to the technicians also?

Ms. Anne Miao: It's interesting that you should mention that because the whole evolution of the CIVA service is a result of migration of pharmacists to a more direct patient-care focus, for example, pharmaceutical care. Hence, these not direct patient care activities are deemed more effective when outsourced.

M^{me} France Gélinas: You lost a multi-million dollar contract when this went to Marchese. Had you had any intention of coming back into this business with Medbuy or had you closed the door on this?

Ms. Carol Bentley: I believe the contract was awarded to Marchese for multiple years and we were regrouping. It was a large contract; however, we do have other customers in other parts of the country, so we continued with our CIVA operations. It was just one contract of many that we have.

M^{me} France Gélinas: Did you—

The Chair (Mr. Ernie Hardeman): Just very quickly, if it's a short question. You have half a minute.

M^{me} France Gélinas: No, it's not.

The Chair (Mr. Ernie Hardeman): Okay. Well, then, that's the end of the questions. Thank you very much and—

Interjection.

The Chair (Mr. Ernie Hardeman): Are you finished? If you're finished, then thank you all very much for being here today and making your presentations. It's very much appreciated and it will be of great assistance as we further deliberate the issue here.

Mr. Mike Oliver: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much.

Nothing else required? Is everybody happy?

The committee adjourned at 1726.

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Lundi 10 juin 2013

Standing Committee on Social Policy

Oversight of pharmaceutical
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La surveillance, le contrôle et la
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ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 10 June 2013

Lundi 10 juin 2013

The committee met at 1522 in committee room 1, following a closed session.

OVERSIGHT OF PHARMACEUTICAL
COMPANIES

The Chair (Mr. Ernie Hardeman): I call the meeting to order. Thank you all, first of all. We thank all of you for being here this afternoon to help us as we proceed in looking at the issues of the day here on the committee, looking at the chemotherapy—here it is. I was looking for the right page: a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies. And with that, thank you very much. We do conduct these hearings under oath or affirmation to make sure that we're getting the facts as you see them.

MARCHESE HEALTH CARE

The Chair (Mr. Ernie Hardeman): I believe the first one is the president. I believe she has been sworn in at a previous meeting, so that swearing-in will be sufficient. With that, we'll turn it over to the Clerk for the rest of the delegation to be sworn in or affirmed.

The Clerk of the Committee (Mr. William Short): I'll just start on my right to left, I believe. So Ms. Francis-Pringle, correct?

Ms. Sophia Francis-Pringle: Yes.

The Clerk of the Committee (Mr. William Short): Did you want to swear an oath or be affirmed?

Ms. Sophia Francis-Pringle: I would rather affirm.

The Clerk of the Committee (Mr. William Short): Okay, so just right hand in the air, please. Ms. Francis-Pringle, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Ms. Sophia Francis-Pringle: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Then Ms. Cuerrier, I believe.

Ms. Kathy Cuerrier: Yes.

The Clerk of the Committee (Mr. William Short): You wanted to swear an oath?

Ms. Kathy Cuerrier: I will.

The Clerk of the Committee (Mr. William Short): And you have the Bible in front of you there?

Ms. Kathy Cuerrier: Yes.

The Clerk of the Committee (Mr. William Short): Thank you. Ms. Cuerrier, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Kathy Cuerrier: I do.

The Clerk of the Committee (Mr. William Short): Thank you. And Ms. Bowles-Jordan: Did you want oath or affirmation?

Ms. Janie Bowles-Jordan: Oath.

The Clerk of the Committee (Mr. William Short): Ms. Bowles-Jordan, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Janie Bowles-Jordan: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Ms. Gilbreath, same thing. Oath? Ms. Gilbreath, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Stephanie Gilbreath: I do.

The Clerk of the Committee (Mr. William Short): Thank you. And Ms. Zaffiro, you'll just remain under oath.

The Chair (Mr. Ernie Hardeman): Thank you very much for that. And with that, we will start. Collectively, you will have 20 minutes to make your presentation. Upon the conclusion of your presentation, we will have some questions, 20 minutes from each caucus. We will start this round with the official opposition.

With that, the floor is yours.

Ms. Marita Zaffiro: Thank you, Mr. Chairman, for inviting me back to assist your committee further. I appreciate the opportunity to address any additional questions you may have. To assist the committee I have invited Marchese pharmacists Stephanie Gilbreath, Janie Bowles-Jordan, Kathy Cuerrier and Sophia Francis-Pringle. I would ask that they now briefly introduce themselves, their backgrounds and their roles.

Ms. Stephanie Gilbreath: Good afternoon. My name is Stephanie Gilbreath. I have been a pharmacist registered with the Ontario College of Pharmacists for almost 15 years. I have worked at Marchese Health Care for over six years and have gained experience in palliative

care, home infusion, diabetes, injections, immunizations, and smoking cessation.

In late 2011, I became the designated pharmacist manager of the Hamilton site of Marchese Health Care. I've also been a preceptor for fourth-year University of Toronto pharmacy students for many years, and am currently a preceptor for an international pharmacist intern.

I was one of six pharmacists involved in checking the mixture breakdowns for the Medbuy admixtures. When Marchese was first awarded the Medbuy contract, we developed a project plan with various tasks of implementation. These included facility needs, IT, regulation, policies and procedures on admixtures, costing, quality measurement, and administration, including hiring. We developed what we call mixture breakdown protocols for making each of the approximately 120 Medbuy products.

The pharmacists worked independently on checking the mixture breakdowns. We then double-checked—sometimes even triple-checked—the other pharmacists' work for each product. Our checking ensured that the proper ingredients, amounts, stabilities, and calculations were all correct.

I believe that having multiple pharmacists involved, checking and consulting with each other, would lead to the most accurate way possible of producing the Medbuy products as described and specified on the list given to us. I believe members of the Marchese team were doing their due diligence to support a successful transition. I was informed that the hospitals had been receiving these items previously and that Medbuy had approved the labels Marchese had developed in response to Medbuy's list.

Ms. Janie Bowles-Jordan: Good afternoon. My name is Janie Bowles-Jordan. I graduated from the University of Toronto in 1990 with a bachelor of science in pharmacy, and I completed a hospital residency and was licensed in 1991 by the Ontario College of Pharmacists.

Between 1990 and 1996, I worked at St. Joseph's hospital as a clinical pharmacist. That's in Hamilton. In 1996, I began working for Marchese pharmacy. I was involved in specialty compounding and formulating custom medications, including sterile preparations.

Between 2000 and 2006, I was the pharmacy services manager for Marchese Health Care in Hamilton. My responsibilities included management of sterile facilities, training staff, and development of sterile compounding procedures to service clients with infusion medications. From June 2006 to the present, I have worked part-time at Marchese Health Care as a staff pharmacist in Hamilton. Since 2010, I have been an adjunct clinical assistant professor at the University of Waterloo's School of Pharmacy.

I was involved in the start-up of the Medbuy transition as part of the pharmacy team. My main responsibility was to research best practices to comply with USP 797 standards and research data for the products on the Medbuy list. At the time, I was informed that the listed products had been produced by the previous provider,

Baxter CIVA. We were not provided, however, with the previous supplier's labels or formulas. Our focus was on the physical stability of the formulations to ensure the highest-quality product.

Our understanding was based on the following: Clinical patient parameters were not provided and we were neither able nor required to check doses; policies and procedures for administration to patients were based on each individual hospital's standards; and oncology pharmacists in hospital would be involved in these clinical responsibilities.

Ms. Kathy Cuerrier: Good afternoon. My name is Kathy Cuerrier. I am a licensed pharmacist and received a bachelor of science in pharmacy from the University of Toronto in 1991.

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I have worked part-time at Marchese Health Care since 2010. Between 2008 and 2010, I worked at Marchese as a relief pharmacist. I have been involved in dispensing, infusion services, special health product services and medication management.

I also had some responsibility for checking the mixture breakdown protocols you just heard about from Stephanie and Janie. As she said, when Marchese was awarded the Medbuy contract, a number of pharmacists checked and rechecked the preparation procedures to ensure that all procedures and calculations were correct.

We were guided by the list of products provided by Medbuy and the labels we prepared that were approved by Medbuy. Since the admixtures we prepared were not patient-specific, we deferred all clinical considerations concerning dispensing, administration and management to the hospital professionals who would deal with individual patients.

Ms. Sophia Francis-Pringle: Good afternoon, ladies and gentlemen of the committee. My name is Sophia Francis-Pringle. I'm a pharmacist qualified in Ontario. I was originally educated at the University of Technology, Jamaica and later at the University of Florida, Gainesville, USA. I hold a doctor of pharmacy postgraduate degree from the University of Florida.

I'm also a board-certified ambulatory care pharmacist and a certified geriatric pharmacist. I was granted certification of licensure as a pharmacist by the Ontario College of Pharmacists in 2010.

I was employed full-time by Marchese Health Care from May 2010 to May 2012. Before working at Marchese Health Care I worked in the Cayman Islands for seven years in various capacities as a pharmacist.

While at Marchese, I was involved in checking the mixture breakdown protocols that my colleagues have spoken about. I agree with their comments about being guided by the list of products provided by Medbuy. I also agree that clinical considerations respecting dosage were deferred to hospital professionals.

The Chair (Mr. Ernie Hardeman): Thank you. Back to you.

Ms. Marita Zaffiro: Thank you. I would also like to address a number of issues that have arisen since my last appearance:

(1) Why did Marchese Hospital Solutions supply concentration-non-specific gemcitabine and cyclophosphamide?

(2) Why did Marchese Hospital Solutions think the IV bags would be used as single doses?

(3) Why was outsourcing to Marchese Hospital Solutions appropriate?

(4) Why Marchese Hospital Solutions had appropriate standards in place.

(5) Why Marchese Hospital Solutions' pricing structure is consistent with high-quality admixtures.

As I stated when I first appeared before the committee, our belief was that the chemotherapy drugs were intended for a single patient. This was a good-faith and reasonable understanding on our part for a number of reasons.

The obvious starting point was our contract with Medbuy. The contract specified the services Marchese was to provide. As you know, the contract contained an alphabetical list of about 120 admixtures. This list of preparations was the basis of our understanding of the non-concentration-specific nature of gemcitabine and cyclophosphamide.

Medbuy listed the preparations in two basic formats: Some were listed in concentration-specific format; other, and indeed most, preparations were listed in concentration-non-specific format. This included various IV solutions of antibiotics, amino acids and stomach acid suppressants.

In listing the two chemotherapy drugs at issue in a concentration-non-specific format, this suggested to us that the contents of the IV bags for these preparations were intended for use in a single patient.

As part of the RFP process, Marchese was asked to supply a set of sample labels. Medbuy provided copies of Marchese's proposed sample labels to the committee. Those initial sample labels submitted as part of the RFP process were exactly that: samples. They were examples of all the possible data fields on the labels which could be populated if desired, and this included concentration specificity.

After the sample label formats were approved, Marchese then focused on Medbuy's list as contained in the contract. It described gemcitabine and cyclophosphamide in a concentration-non-specific format.

After our technical review process, we prepared a complete library of 124 labels for Medbuy's approval. I want to emphasize to the committee that the description of admixtures on the list was prepared by Medbuy without input from Marchese.

It was not our role to review Medbuy's list to determine whether it was clinically appropriate. We understood that Medbuy's pharmacists and member hospitals had made that determination before the list was made a schedule to the contract. Our responsibility was to ensure that our labels and admixtures conformed to what was ordered, as specified in the list which was a schedule to the contract. The labels Marchese prepared for all admixtures, including cyclophosphamide and gemcitabine,

were sent to and approved by Medbuy's pharmacy team and their hospital members before any admixtures were shipped.

Marchese was never provided copies of Baxter's labels or mixture breakdown formulas. We were told that they could not be provided to us for proprietary reasons. Had we seen Baxter's labels, we would have noticed the difference. We would have inquired as to why there was an apparent change. Baxter's labels for these two preparations specifically indicated a milligram-per-millilitre concentration statement, which we understood to be a concentration-specific admixture. Our preparations did not include this statement, as it was not included in the Medbuy admixture list.

Similarly, we understood from Medbuy that the hospitals had been given our labels for review and training purposes. Had Medbuy or one of the hospital pharmacies noticed the difference, the issue could have been raised and addressed before preparation and delivery under the contract.

As it was, we understood that the majority of preparations, including cyclophosphamide and gemcitabine, were to be supplied by Marchese in a concentration-non-specific format and that this was acceptable to Medbuy and its hospital members.

Also, in January 2012, a month before the contract commenced, there was an exchange between a Marchese pharmacist and Medbuy's manager of clinical services and patient safety referring to the chemotherapy preparations. The email string, copies of which I have brought with me today and provided to the Clerk, concerns the attachment of various lines or tubes to the bags. We had raised with Medbuy the possibility of attaching a line to the bags as a safety precaution to protect nurses who administer them from any unintentional exposure to these toxic drugs. Medbuy's representative said he didn't want the lines because he expected different hospitals might have different requirements. He stated in this email, "Members will still be putting on a patient-specific label in the pharmacy and can attach a line, if desired, at that time."

This also suggested to us that Medbuy's understanding, and therefore our understanding, was that these bags would be used for a single patient.

I would like to respond to questions raised by the committee as to whether outsourcing the preparation of admixtures is an appropriate practice or whether this should always be undertaken in hospitals.

Dr. Thiessen discussed this issue with the committee after visiting the MHS premises in Mississauga. He described the process for reconstituting cyclophosphamide and gemcitabine. He indicated that it can take up to four hours to prepare, which can be a burden on a busy hospital pharmacy department. Dr. Thiessen's opinion was that it was a "big advantage" to have an outsource supplier prepare admixtures for hospitals.

I agree with Dr. Thiessen's observations. Providing high-quality admixtures is complex and technical. It is better undertaken by specialists in sterile, state-of-the-art

facilities, leaving hospital pharmacies to focus on direct clinical patient care.

I would also like to respond to general questions about the quality of Marchese Hospital Solutions' facilities and processes, as well as any suggestion that our practices, staffing or products were somehow inferior to the previous supplier or others in the industry.

Dr. Thiessen informed this committee that, "Only quality, approved pharmaceutical products and diluents were used." He continued, "There is no evidence of any malicious or deliberate drug-sparing dilution in preparing the bags of cyclophosphamide or gemcitabine by Marchese."

Dr. Thiessen told the committee about the benefits MHS brought to hospitals by providing admixing services. He said we have the "finest facilities" and added that no hospital he had visited had a facility to match ours. He commented that it is "splendid in its configuration, in all the things that they have as checks and balances. They have very detailed requirements around how things are produced."

Dr. Thiessen is not alone in his views that MHS is well-equipped to supply admixture services. Medbuy member hospitals have inspected our premises. The consistent testimony before this committee has been that our processes and standards are of the highest level. Our customers have repeatedly told us we operate at a high professional standard.

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The Marchese team of pharmacists and technicians collectively bring years of professional experience to bear. However, they are only one third of the triumvirate described by Dr. Thiessen. Pharmacists at Medbuy and in the hospitals are also engaged, and each has a different role. The system is designed for the three parties to work together, but each with distinct roles. We must all ensure preparations ordered by a GPO are precisely those required by its member hospitals. Furthermore, we must communicate to ensure that the admixture service prepares exactly what is ordered by the hospital, and that the hospital pharmacists fully understand the admixture supplied to them.

The hospitals have clinical contact with patients. Marchese Hospital Solutions has no individual patient information. Therefore, our role does not include any assessment of clinical factors.

The incident demonstrates that the system did not work in this case, but the failure could have been avoided. A simple line in the contractual requirement, milligram per millilitre, would have provided the appropriate concentration specificity, and none of us would be here today. An opportunity to review and compare our label with that of our predecessor would also have prevented the problem.

I would now like to deal with the question of the pricing of our admixtures.

Last week, after Baxter Corp. appeared, concerns were raised about our pricing for the two chemotherapy admixtures. It is misleading to suggest that there is any link

between the incident and any difference in price between Baxter CIVA and MHS. As specified in the RFP process, we were not required to include in our price the cost of the drugs included in the admixtures, only the cost of labour, overhead, containers, packaging materials and shipping. We believed it made sense to price based on the size of the bag that preparations would be delivered in—50, 100, 200 or 250 millilitres—rather than pricing individual admixtures based on the type of drug, amount of processing time or value added to the hospitals.

The same meticulous quality control process was set up in our facilities to prepare all admixtures no matter what drug was admixed or what preparation steps were involved. There is no basis in fact for any suggestion that the miscommunication on concentration specificity had anything to do with pricing. There is no rational connection between pricing and this incident, in our opinion.

So what happened here? We still have to wait for your report and Dr. Thiessen's report to understand everything, but what we now all know is that there was miscommunication and an unsuccessful transition that resulted in needless anxiety to many patients. Marchese took the position early on that we could best serve patients by only talking about things that we were certain of. We decided that we should focus our energy on working together with the other members of Dr. Thiessen's triumvirate to understand what happened and how to prevent a recurrence.

However, in spite of this, we were publicly accused of consciously watering down cancer drugs for profit—this was not true, as Dr. Thiessen noted; manufacturing sub-standard products—this is not true, as the committee has already heard; ducking regulations—the evidence clearly shows that nothing could be further from the truth; and disregarding the health of patients—which is the exact opposite of Marchese's philosophy. Patients are the reason we are all involved in health care.

We all owe a debt of gratitude to the people in Peterborough who very quickly and competently saw that there was a mismatch between their hospital's expectations and the admixture in their hands. From the moment we heard about the issue, we have been trying to fully understand what went on and help fix the system so that no patients ever have this experience again.

We would be pleased to answer your questions.

The Chair (Mr. Ernie Hardeman): Thank you very much for your statement today. With that, we will start with the questions from the official opposition.

Mrs. Jane McKenna: Hi. Thank you so much for coming back, Ms. Zaffiro. Just a few questions from myself, and then Ms. Elliott will take over.

When we had Baxter in here, they said that they had been doing this process for 27 years, and when they found out that they had lost to you, they asked why they had lost, and they clearly told them that it was not the fact that it was the price; it was everything to do with the label. So I said to them, "Gee, after 27 years of being in business, I would want to know specifically what that was, just because"—you know, that's your business. So

27 years, and all of a sudden, now you've got a label issue.

I think you've said this already, but at any time did you see their label at all—Baxter's label?

Ms. Marita Zaffiro: No.

Mrs. Jane McKenna: So the next thing is, when you were in here before, you had mentioned—the committee has said a few times that when they got the RFP, the label that you had sent over, it was different than when they actually had the delivery of the label. So what was the difference?

Ms. Marita Zaffiro: This is in my remarks.

Mrs. Jane McKenna: Yes, go ahead.

Ms. Marita Zaffiro: We provided sample labels and we populated every field that could be populated. So we have a program where line 1 would be the name of the drug etc. So everyone had every possible piece of information on it so they could see what was possible, along with the bar-coding, the boxed information, the tall man lettering and the other enhancements to the label. So they could see basically the menu of what they could have on their labels, what was possible. Those were the samples of what we could produce.

Mrs. Jane McKenna: Next, do you understand—like this huge difference in pricing. Yours was \$5.60 and Baxter's was \$34. That would have been a red flag for me, but besides that, what is the massive difference from your pricing to their pricing? I know you can only speak on your own, but I'm just saying that's a huge difference.

Ms. Marita Zaffiro: It is. I could only speculate and I'd rather not speculate here.

Mrs. Jane McKenna: No, no, that's fine—

Ms. Marita Zaffiro: If you have to have a business conversation outside—

Mrs. Jane McKenna: Yes.

Ms. Marita Zaffiro: —because it would be pure speculation. I have no idea.

Mrs. Jane McKenna: Okay.

Ms. Marita Zaffiro: I couldn't even possibly say. It wouldn't be right for me to speculate on that, but I think it's a reasonable question.

Mrs. Jane McKenna: Yes.

Ms. Marita Zaffiro: If you had the full analysis—I don't think I said it in my remarks, did I? For example, you may find that they priced on a value-added basis. Chemo is complex. Chemo is dangerous. They might have weighed their pricing in that regard. Forty per cent of the volume I think was cefazolin and 50 millilitres of diluent—easier to do, simple, high volume. So maybe Baxter's price is lower than mine. I don't know. So their pricing strategy could have been vastly different, but we were told the same thing in our debrief, that it wasn't about price, that on price it was very close. So if you added one unit of everything that we quoted on and totalled that up, that may be the case. Again, I'm not privy to that, but that would be one way you could arrive at that and a strategy that might cause that kind of discrepancy.

Mrs. Jane McKenna: Then my next question is, when Baxter was here—because they had the contract prior to going through Medbuy, they continued the process with the hospital like they didn't have a contract. What I mean by that is that they were constantly communicating back and forth with the hospital. They just continued what they were doing prior to having Medbuy come in. So was your relationship with what you were doing similar to what Baxter was doing, communicating back and forth with the hospital? Or yours was just strictly with Medbuy and no communication at all with the hospitals?

Ms. Marita Zaffiro: We had communications back and forth with Medbuy, Medbuy pharmacists, some of the hospital member pharmacists directly and through Medbuy during that transition process, and that's what informed the final label set. So that communication I read to you was once of those communications.

Mrs. Jane McKenna: Okay. So the communication going back and forth was strictly yours with Medbuy?

Ms. Marita Zaffiro: Medbuy was the quarterback, I guess I would say, in that transition. So the expectation was not that we visited 30 hospitals to talk about 124 products before we prepared them; that would be pretty impossible. These products were already specified. They'd been using them. They had developed them over those 27 years with Baxter as the only provider in the market, so this was an opportunity to look at, can these very technically specific products be prepared by another provider at a better price?

Mrs. Jane McKenna: I'm just saying for myself, like if I had a financial planner, that would be a broker that should know the product they're selling and the product they're explaining to me. Do you feel that Medbuy being the broker, knowing what they were getting from you and also selling to the hospitals, your communication was—I realize that it wasn't obviously what it was supposed to be. But to me, I'm not sure how you would have known the questions to ask if they didn't give you all the details on what to ask. To me, that's where the communication drops because—I'm not an insurance person, so I don't have all the questions to ask. It's the person who is the insurance broker who tells me what to ask so that I know what the heck I'm buying.

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My question to you is: When you're in that situation—because this was your first situation here; you hadn't done it before. You were the ones who actually came to Medbuy to say that you could bid on this RFP. Did you have enough information to come to the table with that, or did you feel that it was up to Medbuy to educate you on what you needed to know?

Ms. Marita Zaffiro: I think that Medbuy, through their hospital members, who are Medbuy—if they've delegated their diligence to the pharmacists at Medbuy. But we have a chain of pharmacists here. So our role was the technical, quality, accuracy and consistency of the final product, and we used what we had available to us to define what that was and we confirmed that with Medbuy.

Medbuy, as we said, took the label set and any information that we shared—that would be our expectation—back to the hospitals. So we feel that we've had a process that has taken multiple pharmacists' brains and experience to work both independently and to consult, to question and to create questions that went back to Medbuy, and then to bring that back to our final product. The reflection of that work is the label set, and the opportunity to identify that these two products were out of alignment was the lack of a specific concentration that pre-existed on Baxter's product. So if what happened in Peterborough happened with the very first shipment in the very first hospital and the very first dose, then we would have been able to make the product that was required. It was a different product, and it would have a different code, but we would have been able to respond in a very short time in that regard.

Mrs. Jane McKenna: Okay. Christine, go ahead. That's good for me, thanks.

The Chair (Mr. Ernie Hardeman): Ms. Elliott.

Mrs. Christine Elliott: Thank you. I'd also like to thank you, Ms. Zaffiro, for coming today with your pharmacist colleagues. I'd like to just ask a few more questions along the same lines as what Ms. McKenna was asking you. When you first received the RFP, can you explain to us the process of due diligence that you went through? What happened in order for you to be able to put your proposal together?

Ms. Marita Zaffiro: First of all, prior to the RFP being released, you're aware that they released a notice, I guess, under procurement that said, "We think there's only one company that can provide this. If you think that you can offer an alternative, let us know." We indicated that we thought we had the expertise to do that based on our many years of doing sterile intravenous products to the home care market as CCAC providers. So we indicated that. Medbuy came and inspected our current facility in Kitchener and was satisfied that, indeed, we could provide that service. I'm not sure that we were known to Medbuy, per se, before that.

When we responded to the RFP—and we have a lot of experience in responding to RFPs, because the value-for-money competitive model that CCACs use is very, very well developed. We would have talked about what our experience was; what our quality systems were; what kind of KPIs, or key performance indicators, we would monitor; how we monitored customer feedback—in this case, it would be hospitals—how we tracked that and what our record was; what our staffing was; what our experience was etc.

Most importantly we would have looked at that list of products in G2 and said, "Can we make these?" So, again, technically, we had experience with various types of products, and we felt that we could make these products in our sterile facilities.

Mrs. Christine Elliott: Did you have any face-to-face meetings with Medbuy before you submitted this proposal with respect to these two particular products?

Ms. Marita Zaffiro: No. A lot of it was handled by our general manager, and I don't think that we did. We

had some communications because this proposal was indicated or anticipated to come up much earlier than it did, and there was a bit of a time pressure, I believe, because the contract with Baxter was expiring. So it came out, it had a fairly short time to respond and then it was evaluated quite quickly. And once it was awarded—again, a very short time to implement.

Mrs. Christine Elliott: Okay. And so you based your decisions with respect to the proposal on the understanding—and most of your document talks about your understanding that they were going to be single-use bags of solution. Was that ever specifically discussed with Medbuy? Did you ever specifically ask that question and get an answer to that?

Ms. Marita Zaffiro: I think the contract actually specifies that these are single doses to patients, if I recall. These are single doses. The majority of products are. I think the logic would tell us that if they weren't, that would be specified as multi-use product. That would have been the important factor to have been told.

Then we're looking at all sorts of different considerations if this was a multi-use product. I mean, some of the research—I'm not sure why you would take a cytotoxic product and then further manipulate it. I understand that these are very patient-specific in terms of their dosage calculations, so it would probably make sense to just be done in the hospital to begin with. The value of doing a cytotoxic and then further manipulating it and taking the risk around expiry dates, sterility etc., once you're using it in any way, it invalidates everything that we've done from a quality control perspective and any control we had or warranty over that, as soon as it's accessed a second time.

Mrs. Christine Elliott: Okay. My next questions relate to the pricing issue. I heard from the previous question that you didn't want to speculate on why there was such a discrepancy in price.

Interjection.

Mrs. Christine Elliott: Yes. But did Medbuy, in the whole process, ever come back to you at any time and say, "Are you really sure this is your price? What's included in the price?"

Ms. Marita Zaffiro: Not to my knowledge.

Mrs. Christine Elliott: Did they ever make any inquiries?

Ms. Marita Zaffiro: Not to my knowledge, no.

Mrs. Christine Elliott: Okay. Next, with respect to the discovery of the problem by the people in Peterborough, our understanding through the course of hearings here is that there were several conversations between one of your pharmacists and a pharmacist both at Peterborough as well as at the Lakeridge cancer centre. Can you identify who that person was?

Ms. Marita Zaffiro: I think they're up next.

Mrs. Christine Elliott: Okay. So can someone speak to that?

Ms. Marita Zaffiro: What would you like to know? I'm sorry.

Mrs. Christine Elliott: Well, I'd like to know what the nature of the conversations was, if it was the same person who spoke to both the person in Peterborough and the pharmacist at the Lakeridge—

Ms. Marita Zaffiro: I believe so.

Mrs. Christine Elliott: —cancer society and the nature of the conversation.

Ms. Marita Zaffiro: We have Kawther Salman, who's a pharmacist, and Roberta Young, who will be speaking to you after we're done. They're going to tell you in detail about who they spoke to and what those conversations were about.

Mrs. Christine Elliott: Okay.

Ms. Marita Zaffiro: I think that would just be clearer because—

Mrs. Christine Elliott: Sure, that's fine. I just wanted to make sure that we covered that.

Another part of the proposal that you submitted was an amount of \$20,000 that was going to be included as, I believe, a donation—

Ms. Marita Zaffiro: The research and education fund?

Mrs. Christine Elliott: The research and education fund. Can you tell us how you came to that figure and whether that's something that you've ever done before?

Ms. Marita Zaffiro: No, that was a requirement of the contract. Again, this was the first time we were doing an RFP with a GPO for hospitals. We took a look at what our contribution needed to be, and whether that \$20,000 came out of the price for the products or came as a separate allocation to their fund, that was basically a neutral decision. Again, the customer indicated that this was how they wanted us to quote on this service.

Mrs. Christine Elliott: Yes, I was just wondering how you came to the \$20,000 figure.

Ms. Marita Zaffiro: I have no idea, really. I didn't make the call, exactly, but it was looking at the total contribution—what did we need—that we felt we needed to cover our costs, as indicated in my statement and our return, and what amount did we want to take out of that to actually put as an allocation to this fund, since that's what they were asking for.

Mrs. Christine Elliott: Thank you. Those are all my questions for now.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Gélinas.

M^{me} France Gélinas: Thank you for coming back. I think you've put it really clearly that the list that you got, some of the 120-some products there were concentration-specific. I have the list in front of me. I can see—I don't know how to pronounce this—fentanyl, 10 micrograms per millilitre. Then they're asking in 0.9% sodium chloride and they want it in the 100-millilitre bag. By reading this, you know that they want concentration-specific.

Ms. Marita Zaffiro: I have to see what you're reading from there.

M^{me} France Gélinas: It comes from your—it has the little X beside it.

Ms. Marita Zaffiro: Sorry, which one is—the fentanyl?

M^{me} France Gélinas: The first one.

Ms. Marita Zaffiro: The first fentanyl? Right—

M^{me} France Gélinas: Correct. But they're all the same—

Ms. Marita Zaffiro: —10 micrograms per millilitre, and 1,000 micrograms in the bag. Right.

M^{me} France Gélinas: Right, as in that would indicate—

Ms. Marita Zaffiro: That's a specific concentration. 1600

M^{me} France Gélinas: That's concentration-specific. It happens to be just two products underneath the cyclophosphamide, which said, "Two grams in 0.9% sodium chloride, 100 millilitre bags"—and this one is not concentration-specific.

Ms. Marita Zaffiro: What I find interesting under the Cs is that you go from cloxacillin and a whole row of antibiotics right to cyclophosphamide, without any differentiation. It's an alphabetical listing, with no suggestion, by product categorization, that these chemo products are differentiated from the other products I mentioned that are concentration-non-specific, be they antibiotics, stomach acid suppressants, amino acids etc. When we looked at it, very quickly our eyes went to the concentration-specific—milligram per millilitre, extra information etc.—to understand that these products needed to be very concentration-specific because of their therapeutic index. We confirmed, in our dialogue with Medbuy, through emails and conversations, that that was the case: that the products we identified on that list as concentration-specific were the only products that are concentration-specific.

M^{me} France Gélinas: Had this list said "four milligrams per millilitre," none of us would be here today?

Ms. Marita Zaffiro: It's actually not four milligrams per millilitre.

M^{me} France Gélinas: It's 0.38?

Ms. Marita Zaffiro: Right.

M^{me} France Gélinas: Yes, 38 milligrams, or whatever they would have wanted it to be.

Ms. Marita Zaffiro: We're aware that Baxter's label on the gemcitabine not only had a concentration, it had a funny kind of volume on it. I don't know if you're aware. It said 105-point-something millilitres, and we understand why that is now. Those are a couple of pretty significant indicators of a very unique label for that particular preparation.

M^{me} France Gélinas: I take it that you have followed the proceedings here. You saw how Medbuy got that list that they sent out.

Ms. Marita Zaffiro: How did they get that list? Remind me.

M^{me} France Gélinas: It's in Hansard from last week, when we were talking to Baxter. It's Baxter that supplied the list to Medbuy, and then Medbuy took the list. I asked Baxter if there had been any changes to the list. Baxter affirmed that, no, the list is exactly the way they had

submitted it to Medbuy. Medbuy took the list of these 120 products that they used to get from Baxter and they put it out for tender, and you answered to this. The issue of checking which one needed to be concentration-specific was not picked up at any point.

Ms. Marita Zaffiro: It was not picked up—I'm sorry? By whom?

M^{me} France Gélinas: It was not picked up, as in Baxter gave that list to Medbuy, Medbuy didn't ask questions, and it took that list and put it back out without ever questioning if some of them should be concentration-specific.

Ms. Marita Zaffiro: There were products on there that were actually designated as concentration-specific—

M^{me} France Gélinas: Because they came from Baxter's list that way.

Ms. Marita Zaffiro: Do you know why they wouldn't have had that piece of information that was on their labels on the product list they gave Medbuy?

M^{me} France Gélinas: No.

Ms. Marita Zaffiro: I know it's not my place to ask questions.

M^{me} France Gélinas: No, they didn't.

Moving on, you took it for granted that the list you had in front of you was clear and that if they wanted concentration-specific, it was written, and if it was not written, it's because they did not need concentration-specific.

Ms. Marita Zaffiro: We took it as our starting point. We had verbal conversations with Medbuy to identify, "Are we correct in our assumption that these are the only concentration-specific products?" That answer was, "Yes, you are correct." So that was how we fed our interpretation of that list back around the issue of concentration specificity.

M^{me} France Gélinas: How can I have proof that this discussion happened, that you asked if there were any other concentration-specific products and you were told, "The list is the list"? Are there any facts to support this?

Ms. Marita Zaffiro: Yes, there are emails.

M^{me} France Gélinas: There are emails? Would you share those with the committee, please?

Ms. Marita Zaffiro: Of course.

M^{me} France Gélinas: Thank you. So your starting point was the list that you got. You went back to Medbuy and asked, "Anything else that needs concentration-specific?" Do you remember if any other products needed to be adjusted?

Ms. Marita Zaffiro: Not that I recall. The team did most of the work. Was there anything else that was non-specific—

Interjections.

Ms. Marita Zaffiro: I don't believe so.

M^{me} France Gélinas: No?

Ms. Marita Zaffiro: It's been a while now, so—

M^{me} France Gélinas: I realize. Okay, so you took it for a starting point, but that wasn't enough. You went to Medbuy and checked: "Anything else? Any concentration-specific?"

The answer back to you was no, so you went to work. You felt reassured because them telling you gave the assurance—

Ms. Marita Zaffiro: There are five chemotherapy products; three of them are expressed as concentration-specific and made as concentration-specific. So in the context of our reasonable judgment and the judgment of six pharmacists or more in the cross-checking of calculations and the context of what our role was, that's the conclusion that we came to. I think one more piece of information might have saved everybody a lot of distress.

M^{me} France Gélinas: You're not kidding.

When you were talking to Medbuy and asking them if there were any other products that should be concentration-specific, who were you talking to?

Ms. Marita Zaffiro: I wasn't talking to them, but we talked to their pharmacist team, so Ron Swartz, Ann Kelterborn—I think there are a couple of other people; Maria somebody. I don't know them, but I can get you that information.

M^{me} France Gélinas: And you're a pharmacist?

Ms. Marita Zaffiro: I'm a pharmacist.

M^{me} France Gélinas: You're a pharmacist and you were talking to other pharmacists. You—

Ms. Marita Zaffiro: I wasn't, but my pharmacists were talking to other pharmacists. I was not—

M^{me} France Gélinas: Okay—were talking to other pharmacists.

Ms. Marita Zaffiro: Yes.

M^{me} France Gélinas: And we will have email trails of that to show that pharmacists answered back, "No, if we wanted concentration-specific we would have told you."

Ms. Marita Zaffiro: Well, those aren't their words, but there is evidence there that we asked the question and received an answer.

M^{me} France Gélinas: And received an answer.

Ms. Marita Zaffiro: Yes.

M^{me} France Gélinas: Okay. Do you want to go?

Ms. Cindy Forster: Yes, thank you. Thank you for being here again today. I'm going to put on my nurse's hat, and I'd actually like to ask the pharmacists who were involved a question, particularly about the fact that you thought this was a single-patient dose bag of an oncology pharmaceutical.

Did you ever second-guess yourself to say, "There is too much drug in this bag for one patient"? Because we heard from Baxter and we've heard from basically every witness that has been here that the amount of drug that was in that bag was enough for a six-foot, 900-pound man. As somebody who has administered medications for many years in a variety of departments, I often questioned myself or questioned a colleague if I thought that there was perhaps an error in the dosage of a drug ordered. That's my question. If I could start with Janie Bowles-Jordan.

Ms. Janie Bowles-Jordan: I came into the process to do research and evaluation. Because I came in in January of the process, a lot of the questions had already been asked of Medbuy and I was informed that yes, the

concentration-dependent products had been identified and we were not responsible for checking dosage because these have been long-standing product items. We were just going to continue the contract and providing quality product, so the focus was on quality, stability, physical and chemical products—

The Chair (Mr. Ernie Hardeman): If I could just stop you for a moment, could you speak a little bit more into the microphone so the rest of the world can hear?

Ms. Janie Bowles-Jordan: Sure. Thank you. The clinical stability had already been vetted, and these had been long-standing products. We were going to be focusing on the physical stability and the drug stability, so we were providing quality products to the hospital that were of a high standard.

Ms. Cindy Forster: Did you have any experience from your past with oncology drugs?

Ms. Janie Bowles-Jordan: I had very limited oncology experience when I was at St. Joe's hospital in Hamilton. However, we did have one experience that I'd like to share with the committee where we did ask a hospital about a dose of vancomycin. It's not referring specifically to this chemotherapy situation, but it was a high dose of vancomycin that could cause red man syndrome if given too high. We questioned the dose and we were told back by the hospital—and this was into the contract—"Don't ask questions. Provide the product. We know how we're using it." So it was under our assumption that there were established protocols and procedures that were at the oncology units that had been vetted through other specialists and this wasn't going to address us.

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M^{me} France Gélinas: Do you have any way of showing the committee that this discussion you just talked about happened? Are there emails? Do you remember how you talked to, which hospital, when it happened?

Ms. Janie Bowles-Jordan: I was not the person directly involved with the conversation. However, my colleagues can probably find email trails on that. As far as the rest of what I've just spoken to, if the discussions had happened prior to me coming on board with the team and therefore I think they're in the emails that Marita has spoken to—that we can find and bring up.

M^{me} France Gélinas: Do you remember who had told you this story, where they reached out, thought the dosage was wrong and were told, "Don't ask questions. Just provide the product"?

Ms. Janie Bowles-Jordan: I think some of my colleagues at Marchese Hospital Solutions would be better to speak to than I.

M^{me} France Gélinas: No idea of whom I should start with? You have a big staff.

Ms. Janie Bowles-Jordan: Well, Kawther and Bobbi will be coming after, and they will probably be best to talk to that.

M^{me} France Gélinas: Okay. We'll ask them. Thank you.

Ms. Cindy Forster: Could I ask that same question of Kathy Cuerrier?

Ms. Kathy Cuerrier: My role in the development of the mixture breakdowns and whatnot was not a clinical nature at all. When I came on board, I was asked to make sure that the mixture breakdowns were correct for calculation and that the products we were using were the correct ones and that we were following protocols and everything to provide, as Janie said, a superior product, to make sure we were doing everything correctly in the technical sense.

I at no time had any idea that I was to be doing any clinical checking. That was not my role as a pharmacist on the team.

Ms. Cindy Forster: Is there not something though—we heard about last week, kind of in the world of pharmacy, that you go back to and check against—I can't remember what the word in it was now. It's some kind of process that you go back and check your admixtures against.

Ms. Janie Bowles-Jordan: I could probably speak to that. Usually, if we were getting a patient-specific drug, we would be very diligent in checking allergies, weight, dosage and being very specific on the route. We do that with all of our drugs, whether it's infusion or oral dispensing. In this case, we were not given patient-specific information, so we couldn't check if the dose was above an average weight or in what conditions it was being used for, because we didn't have renal function, we didn't have surface area, we didn't have weight. So we didn't have the clinical capacity to perform those functions that we would do on a patient-specific basis.

Ms. Cindy Forster: And what about your oncology experience, oncology pharmaceutical experience?

Ms. Kathy Cuerrier: Mine?

Ms. Cindy Forster: Yes.

Ms. Kathy Cuerrier: I worked at the Juravinski Cancer Centre outpatient dispensary for two years, from 2006 to 2008, so I was involved with providing supportive medication to cancer patients. I didn't have any direct experience with IV chemotherapy at all. There were a few oral chemotherapy medications that I dispensed to patients.

Ms. Cindy Forster: And Stephanie Gilbreath, could I ask you the same kind of two questions?

Ms. Stephanie Gilbreath: Sure.

Ms. Cindy Forster: Your experience with oncology pharmaceuticals and—

Ms. Stephanie Gilbreath: My oncology experience is limited. As a student years ago, I was preparing chemo, but that was a long time ago. As I stated in my statement, I have some home infusion experience from working at Marchese, where we did a bit of chemo. That's about it.

Ms. Cindy Forster: And Sophia, could I ask you the same questions, please?

Ms. Sophia Francis-Pringle: Very limited; pretty much none. My experience has been in general pharmacy, ambulatory care, but not chemo—oncology-specific.

Ms. Cindy Forster: Okay. Thank you.

M^{me} France Gélinas: To change the topic completely, I want to come back to the \$20,000. You have prepared

medications for third parties for a long time. You have a contract with CCACs, you have an entire business of doing this. Have you ever been asked for that kind of money in other contracts?

Ms. Marita Zaffiro: No, we've never been asked. Again, we are very supportive of inter-professional collaboration and education. We also try to be very innovative as we've been pioneers in providing to home care.

So among innovating the depot delivery system and the predecessor IT system that allowed CCACs to create POs of their own, we, at one point, provided a bursary of \$5,000 in our proposal that was to be used to have a nursing agency staff member, a Marchese pharmacy staff member and a CCAC staff member do some education jointly at a particular conference. So that's the closest that we've ever come to when we proposed that.

M^{me} France Gélinas: And did that ever come to fruition?

Ms. Marita Zaffiro: Did we ever use it?

M^{me} France Gélinas: The bursary. The \$5,000.

Ms. Marita Zaffiro: I can't remember for sure. It was a long time ago, and it's not something that we continued doing. We started when it was still the home care program. It was very collaborative. Over time, there became very strict requirements around that kind of thing. That wasn't requested and you didn't have the opportunity to make innovative or different kinds of suggestions. It was very prescriptive.

M^{me} France Gélinas: And, in your dealings with hospitals specifically, had you ever been asked to make that kind of a—

Ms. Marita Zaffiro: No.

M^{me} France Gélinas: No. Okay. So we'll save our minute.

The Chair (Mr. Ernie Hardeman): Thank you. That concludes your time.

M^{me} France Gélinas: Oh.

The Chair (Mr. Ernie Hardeman): Thank you.

Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Thank you for coming back, Ms. Zaffiro.

I'd like to turn to the issue where the miscommunication occurred, which is, of course, this concentration-specific format. You used that in your presentation and you have it sort of in italics: "concentration-specific." Is this something standard in the practice of pharmacy that "concentration-specific" is a widely recognized term, and you mean per smallest unit—in this case, per millilitre?

Ms. Marita Zaffiro: I think it's what we recognized in differentiating the items listed on Medbuy's schedule. We saw it as a key differentiator of the products as they were listed. Now, in concentration-specific—it's an important factor because, as we said, unit dose in a mini-bag, you infuse the entire bag to get the entire dose.

So in the absence of other information and the context of this service and this transition, we were not looking at the existence of multi-dose bags. We would have thought we would have been informed if one of these bags was

multi-dose. It would have had a different consideration around a preservative, potentially. So that was the assumption based on how the information was presented.

We make oral solutions. We make other sterile solutions as well. If we are making a reservoir from which we then make patient-specific dilutions in our home care or in our specialty compounding business, we use preservatives. We make them concentration-specific, and we label them as such.

Ms. Helena Jaczek: See, to the average person—I am a physician. If I saw a label that said four grams of the compound in 100 millilitres, I would mentally just make the division and assume it was 40 milligrams per millilitre. So am I somehow an outlier?

Ms. Marita Zaffiro: No, I don't think so. I really appreciate that, because I have a very good friend who is the VP of nursing at a hospital. I was relaying to her this particular situation, and she said to me, "Do you mean that bag that we hang that says X antibiotic grams in 100 millilitres isn't exactly four grams per millilitre?" She was very surprised, and she's a very seasoned both administrator and nurse. I said, "Yes. That's the reality."

So what it really brings home, for all of us, I think, is the need for a national labelling standard. We need to have the same understanding. Whatever logic or convention we apply against it—I mean, we don't know that one hospital doesn't interpret something different than another.

The P&T committee would educate the professional staff, I believe, on how do you read these bags. What do we mean when we say this? And to the degree that that's effective, and to the professionals or support staff who actually understand that, there are probably many, many gaps and many opportunities that are subject to interpretation.

At the end of the day, it is an art, and we want it to be more of a science, I think, in terms of how we label these products.

Ms. Helena Jaczek: So you're looking forward to Dr. Thiessen's recommendation?

Ms. Marita Zaffiro: Absolutely.

Ms. Helena Jaczek: Now, when Baxter came in, they made a major point of—and perhaps Ms. Forster was getting at this—that they use the product monograph in terms of the reconstitution of gemcitabine. Did that occur to any one on the team whether that might be a way of reconstituting this product?

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Ms. Janie Bowles-Jordan: We always use the product monograph as our basis. We use evidence to support all of our reconstitution and our monographs, so if there is a monograph that states specific dilution requirements, that's always put as part of our procedures.

Ms. Helena Jaczek: But then, as they explained to us, if you do it the way the product monograph suggests you would end up with 38.5 milligrams per millilitre because you have to replace the displaced volume from the powder in the vial.

Ms. Marita Zaffiro: Yes. I think we understand that, but again, in the context, we were putting that into a pre-

filled mini-bag and drawing out a portion to create all that, so the final volume was that 105 plus the average overfill that would be in that bag.

Ms. Helena Jaczek: But it never occurred to your team that you might want to do it that way?

The Chair (Mr. Ernie Hardeman): If I could just have your attention again, can you speak closer to the mike? Hansard is having trouble picking it up.

Ms. Janie Bowles-Jordan: We have multiple products in our database where we do pull out volume based on that concentration specificity. As you know as a physician, if we're making an antibiotic and you put one gram into a 100-millilitre mini-bag, you're not pulling out volume; the whole bag is hung as one complete unit. If the product has been defined as concentration-specific, we always pull out the volume that we're going to be injecting, and make those adjustments.

In fact, when we were checking the calculations for our mixture breakdown sheets, we were double-checking for that if we were triggered that it was necessary in the process. But if it wasn't meant to be concentration-specific, it's an added step that we don't usually do unless we know it is supposed to be to a defined concentration.

Ms. Helena Jaczek: This gets back, of course, to the question of whether this was destined for one single patient. Again, as a physician, if I'm not very familiar with a drug, I pull down the CPS off the shelf and I look at the appropriate dosage. I guess with such a team it's just surprising that no one did that. Can anyone—

Ms. Marita Zaffiro: Again, we approached it as there were multiple minds. In the context of 124 admixtures, these two admixtures were stated in the convention of non-concentration-specific, and the concentration-specific products were clearly stated differently.

In the context of the work that we were doing and the amount of work that we had to do to effect a transition in 45 days, to have done a clinical review and to have included that on our protocols where we would state, "Here's the minimum dose and the maximum dose, and how you calculate this dose. Here are the indications"—which we're fully capable of doing—would have been a whole other level of requirement that was not designated in the contract, nor do I believe it was expected in any way, shape or form.

Ms. Sophia Francis-Pringle: May I just add that the issue would also be how would we arrive at a particular dose for a particular patient, because we would really need the specifics of the patient in terms of diagnosis, weight and all the other issues, really, to come to that decision. So we honestly weren't privy to all the patient specifics that really have to be considered to arrive at the dose. I know it sounds a bit bizarre, but it's just that when you do consider—for example, if you're filling a routine prescription, you're really given more information than you would have in doing this type of manufacturing.

Ms. Helena Jaczek: I guess it would simply be that if you had the experience that Baxter had originally where

they were in direct communication with hospital pharmacies, you would have immediately understood that this was a stock bag for multiple patients and it was supposed to be concentration-specific, and this is the problem that we're facing, this miscommunication of what was required.

Actually, you're Ms. Francis-Pringle?

Ms. Sophia Francis-Pringle: Yes, I am.

Ms. Helena Jaczek: Attached to your presentation to us that the Clerk certainly handed to me are a couple of extra pages.

Ms. Sophia Francis-Pringle: Oh?

Ms. Helena Jaczek: Yes, and I was just wondering—it was not read into the record. It was attached. It was numbers 6, 7, 8 and 9 under "Process." This is not something that you wanted to discuss with us? Because it does have some interesting information.

Interjections.

Ms. Helena Jaczek: It's not part of the record, but it certainly was attached to mine.

Interjections.

Ms. Helena Jaczek: Anyway, no problem. I'll just leave that with you, but there's some interesting information there.

If we could then just move on because, in fact, Ms. Francis-Pringle, you've alluded to the fact that if it's patient-specific there's a lot more information.

I'd just say, Ms. Zaffiro, I know we heard from Laura Savatter last week about the, I would say, really quite extraordinary efforts that were made to look at the regulatory framework in terms of supervision by the College of Pharmacists, the regulations related to what Health Canada is potentially looking—we've heard this grey zone. Will you welcome this kind of oversight, Ms. Zaffiro?

Ms. Marita Zaffiro: Absolutely. As you may be aware, the college floated initially their regulatory and bylaw changes. We commented on them quite extensively. They then had their meeting and passed their regulatory changes. They are now in the process of creating the standards and forms and processes to actually be able to begin inspections and notifications etc. We've indicated our desire to assist, to comment and to make ourselves available as the first recipient of their inspection. As you had said, our desire was always to be regulated, and so we welcome the opportunity for that regulation to now occur.

Ms. Helena Jaczek: In general, and you've alluded to it, what do you see as the benefits of a procurement process for these types of admixtures outside of the hospital?

Ms. Marita Zaffiro: The benefit, again, is the quality, consistency and accuracy, the competency of trained staff who are doing this all the time, particularly in the complex or toxic products. Again, these particular chemo products don't necessarily lend themselves to be outsourced for patient-specific dose creation unless there were standardized protocols of some sort.

I think those are some of the benefits. They are technical and repetitive. So the ability to use those kinds of

management systems to manage the quality, consistency, repeatability etc. are where the benefit comes from. And if that's a better use of resources, human and financial, then that allows our health care system to benefit from that.

Ms. Helena Jaczek: We'll save our time, Chair.

The Chair (Mr. Ernie Hardeman): Thank you very much. The opposition? No further questions. Then you have to finish, because that's the end of the day. Thank you.

Ms. Janie Bowles-Jordan: I think if I could just add—

Ms. Helena Jaczek: Sure. Go ahead.

Ms. Janie Bowles-Jordan: In the fact that there are USP 797 standards that are becoming compulsory in the US and are in the process of coming into Canada, and in that the facilities have to be very strictly done to meet various bacteria parameters and so forth—it's very hard for a lot of the hospitals to meet this high standard of facility that's required in order to produce these chemical products. In doing that, we can have a specialty area that would meet these specifications and meet the standards.

Ms. Helena Jaczek: Was some of that part of the discussion with Dr. Thiessen when you met with him? So we may see some of these recommendations forward?

Ms. Marita Zaffiro: In the absence of regulation, the management systems and standards that we put in place came from USP 797, OCP, Health Canada etc. We adapted all the available standards—those and more—to put in what we thought was the most diligent and appropriate quality management system for what we produced. That was very important given that we were venturing to provide a very, I think, valuable, needed service alternative to Ontario hospitals.

Ms. Helena Jaczek: Perhaps we could just look at the email that you presented with us, I guess, the email chain from Laura Savatteri to Ann Kelterborn, who was a pharmacist at Medbuy, I presume, that was then responded to by Ron Swartz.

Ms. Marita Zaffiro: Yes.

Ms. Helena Jaczek: Could you just perhaps explain to us what this meant to Laura, and subsequently to you, in terms of that response from Mr. Swartz? How was that interpreted?

Ms. Marita Zaffiro: I guess the key piece of information here was his comment that, "Members will still be putting on a patient-specific label in the pharmacy" on the bags of chemo that we were providing, because the other three chemo products are not in bags. That was a confirmation—not a direct confirmation, but certainly not any kind of indicator that these bags were not patient-specific and are used in that way.

Ms. Helena Jaczek: So the interpretation, in essence, was that the bag as a whole would be labelled patient-specific in the hospital pharmacy, and the assumption was that the entire bag would be used. That was—

Ms. Marita Zaffiro: Which is how the other non-concentration-specific products were—

Ms. Helena Jaczek: So it was sort of a confirmation in terms of your consumption.

Ms. Marita Zaffiro: It was a confirmation.

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Ms. Helena Jaczek: Okay, I understand that. Then you will be sending us—my colleague Ms. Gélinas—the emails to confirm some of this backwards and forwards between Marchese and the pharmacist team at Medbuy.

Ms. Marita Zaffiro: Yes.

Ms. Helena Jaczek: That would be very helpful. We have no further questions.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes your presentation today. We thank you very much for coming in and helping us out again with the process as we move forward through this.

Our next delegation is also from Marchese Health Care: Roberta Young and Kawther Salman. Thank you very much for being here. As with the previous one, we do ask all delegations to be sworn in or affirmed for the presentation. With that, we'll let the Clerk do his thing, and then we will carry on with the rest of the presentation.

The Clerk of the Committee (Mr. William Short): I'll start left to right. Roberta Young?

Ms. Roberta Young: Yes.

The Clerk of the Committee (Mr. William Short): Do you prefer to be affirmed or swear an oath?

Ms. Roberta Young: Oath, please.

The Clerk of the Committee (Mr. William Short): The Bible is there. Ms. Young, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Roberta Young: Yes, I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Ms. Kawther Salman, you requested a copy of the Koran, which is in front of you.

Ms. Salman, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Kawther Salman: Yes, I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. Being the only two witnesses, we will start the presentation. You will have 20 minutes to make your presentation, and then we will have opportunities for questions from each caucus for 20 minutes. This round will start with the third party.

With that, thank you again for being here, and the floor is yours to make your presentation.

Ms. Roberta Young: Thank you and good afternoon, Mr. Chairman and ladies and gentlemen of the committee. My name is Roberta Young. I am known to my colleagues and my family as Bobbi.

I hold a certificate from a pharmacy technician program. I have also successfully completed my Pharmacy Examining Board of Canada, or PEBC, evaluation

examination. I am currently working toward my certification from the Ontario College of Pharmacists as a regulated pharmacy technician.

I have 11 years of retail pharmacy and IV infusion experience. I have been employed by the Marchese companies—either Marchese Health Care or Marchese Hospital Solutions—for five years. Between 2008 and 2011, I was an infusion technician at Marchese Health Care's premises in Hamilton, Ontario. From January 2012 to the present, I have been employed as an infusion technician at Marchese Hospital Solutions'—MHS—premises in Mississauga.

Before working with Marchese, I was employed for two years by a large retail pharmacy chain. I was not involved in any commercial negotiations leading to the contract between MHS and Medbuy. I was, however, involved in recruitment and hiring new staff, purchasing equipment and supplies, and set-up of the new clean room established at MHS's premises in Mississauga to prepare admixtures under the Medbuy contract.

I am familiar with the preparation of MHS's IV bags and have responsibility for ensuring prompt and accurate delivery of our IV admixtures to Medbuy hospitals. I have direct knowledge of the IV bags containing gemcitabine and cyclophosphamide prepared at MHS, based on my experience either preparing or observing preparation of those admixtures.

The following steps were taken by MHS in preparing a 100-millilitre IV bag containing four grams of gemcitabine:

- within a segregated biological safety cabinet in our clean room, we started with a pre-filled 100-millilitre IV bag supplied by Hospira;

- we withdrew two 50-millilitre amounts of saline solution from the pre-filled bag;

- the two 50-millilitre amounts were then injected into two vials, each containing two grams of gemcitabine, to reconstitute the drug;

- after the gemcitabine was dissolved, the contents of the two vials were injected back into the pre-filled bag;

- because the gemcitabine mixtures we prepared were not required to be concentration-specific, the small amount of overfill in the bag was not removed; and

- the final admixture in the bag was delivered to a hospital with the label "4 g in 100 mL," meaning it was not concentration-specific.

In the afternoon of March 20 of this year, MHS received a call from a woman named Judy. I understood that Judy worked in a pharmacy department at one of the Medbuy hospitals. At first, I thought Judy was in Oshawa but later learned she was in Peterborough. Judy had a technical question about our 100-millilitre gemcitabine bags.

The call was originally taken by one of our business people at MHS, Bert Notarius. Bert asked me to participate in the call with Judy when he understood she had a technical question.

In the call with Judy, I explained our process of preparing gemcitabine bags. There was a specific discussion

of overfill and concentration. I indicated that the bag was non-concentration-specific and therefore it was our assumption that it was for single-patient use. I suggested to Judy that someone from the hospital should speak with the Marchese Hospital Solutions pharmacist if they needed further clarification.

Later that afternoon, the Marchese Hospital pharmacist, Kawther Salman, spoke with a Peterborough representative. I will let Kawther explain to the committee her recollection of the communications and describe the timeline from there.

Following the call, Kawther sent an email to me and others. She informed us that she had been told that the overfill created a problem for the Peterborough hospital's infusion pumps. Kawther suggested that we should either remove all overfill from the bags or use sterile empty bags to prepare the solution. A copy of Kawther's email dated March 20, 2013, has been provided to the committee.

Given the communications with Peterborough Hospital, we thought it was prudent to contact London Health Sciences Centre, the largest Medbuy hospital purchasing cyclophosphamide and gemcitabine bags from Marchese Hospital Solutions. The next day, March 21, 2013, Bert called Ian McKechnie, the manager of pharmacy operations at London Health Sciences Centre, to get insight on the way that they were using our chemotherapy admixtures. An email exchange between Bert and Ian followed. That has also been provided to the committee. Ian suggested that I speak with Charlene Jones, the pharmacy coordinator at London Health Sciences Centre's oncology area.

Later that day, on March 21, I spoke with Charlene. In the call, I asked her how the hospital was using our product. I also explained how we prepared the product. I learned from Charlene in that call that our product was being used as a reservoir to create other IV bags at the hospital. In the call, Charlene did not express any immediate concern about the existence of overfill in our bags.

On March 21, 2013, Bert also telephoned Linda Skinner, the pharmacy manager at Lakeridge in Oshawa, to set up a conference call to discuss the issue. Linda informed us later that day that a call would be set up for the next day: March 22, 2013.

On March 22, 2013, at 8:30 a.m., Bert and I spoke with Linda Skinner and, I believe, one other Lakeridge employee who I believe was Janet Slessor. Kawther also participated in this call. In that call, we proposed removing any overfill from the bags, and I understood that the proposal was acceptable to Oshawa. We told them that we needed to address the issue with the other hospitals purchasing these products and would get back to them. In the interim, Linda told us that Lakeridge was halting all orders of cyclophosphamide and gemcitabine.

On Monday, March 25, 2013, London Health Sciences Centre called and asked us to hold all further shipments of cyclophosphamide and gemcitabine.

On Tuesday, March 26, Bert was in contact with Medbuy. A brief summary of facts was sent that day to

Ann Kelterborn, a pharmacist at Medbuy. Ann informed us that she was aware of the concerns raised by the hospital.

On Wednesday, March 27, 2013, Bert and Laura contacted Horizon Health Network hospitals in New Brunswick to inform them of the potential problem. Later that same day, Bert and Laura also spoke with John Devlin, the pharmacy manager at Windsor Regional Hospital.

On Thursday, March 28, Bert sent an email to all Ontario and New Brunswick hospitals offering to change our production processes and labelling to meet their needs for a concentration-specific admixture. These details of my own, and other communications I was aware of, are provided to show the committee that once the problem was raised with one of our admixtures, we did not remain silent. We took the initiative by warning Medbuy and other hospitals about the issue. As another witness, Sandy Jansen from Lakeridge regional health hospital, told you, we were “very open and transparent” with information we provided. Had any hospital, or Medbuy, raised the problem earlier, I am confident that the result would have been the same.

I will try and answer questions that the committee may have.

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The Chair (Mr. Ernie Hardeman): Thank you.

Ms. Kawther Salman: Good afternoon, ladies and gentlemen of the committee. My name is Kawther Salman. I am a pharmacist qualified in Ontario. I was originally educated at the pharmacy school of Baghdad University in Iraq. I came to Canada with my family in 2003. I was granted certification of licensure as a pharmacist by the Ontario College of Pharmacists in 2009.

In the 10 years since coming to Canada, I have worked at a variety of retail pharmacies in the greater Toronto area. I have been employed in both full- and part-time positions as a pharmacist. I have also acted as a relief pharmacist on several occasions.

I first began working, on a part-time basis, with Marchese Health Care in their retail pharmacy in Hamilton in June 2012. In July 2012, I began taking part-time shifts for Marchese Hospital Solutions at their premises in Mississauga. I only began working full-time for Marchese Hospital Solutions in Mississauga in early March of this year. I continue to work one day a week in a retail pharmacy to keep my skills for direct patient care updated.

I was not employed by Marchese Health Care or Marchese Hospital Solutions when the contract with Medbuy was awarded. By the time I began working with Marchese Hospital Solutions in Mississauga, the production processes for IV bags, including bags containing the chemo drugs gemcitabine and cyclophosphamide, were well established.

I worked directly in the clean room at the Mississauga facility, checking preparation of all admixtures for quality, sterility and accuracy. The admixtures included gemcitabine and cyclophosphamide.

On March 20 of this year, Bobbi asked me to speak with Judy, a hospital technician in Peterborough, about our 100-millilitre gemcitabine bags. In the call, Judy asked me about our process for preparing the bags. We spoke about overfill and the hospital's intended use for the bag. In the conversation, I stated my assumption that the bag was intended for single-patient use because the concentration was not specified. In the call, Judy told me the hospital was having difficulty with overfill because their infusion pumps required a specific unit of milligrams in milliliters. At the end, she said that she would speak to the Lakeridge pharmacist and would call me back the next day.

The same afternoon as the call with Judy, I sent an email to Bobbi, Bert Notarius, the business development manager, and Laura Savaterri, a fellow pharmacist, suggesting two possible solutions. My first suggestion was that we could make the gemcitabine solution concentration-specific by removing any overfill from the bag. My second suggestion was that we could order empty sterile bags and inject the reconstituted solution into the empty bag. My email dated March 20, 2013, has been provided to the committee.

Two days later, on Friday, March 22, 2013, I participated in a conference call with two employees of Lakeridge hospital in Oshawa. In that call, we proposed removing any overfill from the bags and preparing an appropriate concentration-specific label. I understood that the proposal was acceptable to the hospital. We could have easily accomplished the change in procedure.

I haven't been directly or substantially involved in the steps taken since the concentration issue was discovered. I am aware that MHS notified the hospitals promptly.

I will attempt to answer any questions posed by the committee.

The Chair (Mr. Ernie Hardeman): Thank you very much. With that, we will start with the third party. Ms. Gélinas, or is it Ms. Forster?

M^{me} France Gélinas: I will start with Ms. Young. Do you have any experience dealing with chemotherapy IV drugs?

Ms. Roberta Young: Before working at Marchese Hospital Solutions in Mississauga, I was trained on chemotherapy by my supervisor in Hamilton. We purchased a chemotherapy training kit that we went through together, and she certified me with chemotherapy preparations.

M^{me} France Gélinas: Same question for Ms. Salman: Have you got any experience working with IV chemo drugs?

Ms. Kawther Salman: Before working with Marchese Health Care, I never got any practical experience with chemotherapy, just theoretical, or knowledge that we got from study in pharmacy school.

When I worked part-time at Marchese Health Care as a retail pharmacist in Hamilton, the pharmacist Stephanie, the designated manager, trained me to check IV admixtures, because she said, “Maybe we will need you to work in our facility in Mississauga.” So the first

training for IV regular order was in Hamilton. In July they sent me to work in the Mississauga facility to check IV fluid or supervise IV fluid preparation. When I went there, Laura was there, and other pharmacists. Laura trained me for checking regular orders. I started in July. My first chemo checking was in August. So I gained my experience from working with people who have experience in chemo preparation.

M^{me} France Gélinas: Thank you. I will go back to you, Ms. Young.

Somebody answered the phone at Marchese when the phone rang, coming from Peterborough, and decided to transfer it to you. Why to you?

Ms. Roberta Young: Because I knew how we made the bags. They were asking specifically what our preparation procedure was, and I could answer that question better than a business manager could.

M^{me} France Gélinas: Okay. And how long was your call?

Ms. Roberta Young: I don't think it was that long. I can't remember specifically how long the call was, but long enough to explain the procedure and answer any questions that they had.

M^{me} France Gélinas: Once you realized that they were using it as a "reservoir"—I think is the word you used—what was the first thought that came into your mind?

Ms. Roberta Young: I suggested that they speak with the pharmacist, because at that point it was out of my scope of practice. I don't make decisions of that magnitude, so I suggested that they speak with the pharmacist to get more of the clinical knowledge that they would require.

M^{me} France Gélinas: And do you know why it went to Ms. Salman as the pharmacist? Just because she happened to be there at the time?

Ms. Roberta Young: She was the pharmacist who was there at that point.

M^{me} France Gélinas: Have you prepared concentration-specific IV products before?

Ms. Roberta Young: I have.

M^{me} France Gélinas: Okay. Do you ever inquire why some are concentration-specific and some are not?

Ms. Roberta Young: With this contract in particular, all of that information was done by the committee of pharmacists and was double- and triple-checked, as they stated in their testimony. At that point, it was just my job to prepare the product to the specifications that they had set out.

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M^{me} France Gélinas: So you felt that you could trust that the committee of pharmacists was asking you to prepare the drugs in the way they should have been?

Ms. Roberta Young: Correct.

M^{me} France Gélinas: And you held that in trust because that's the way it works, because you were told?

Ms. Roberta Young: Because of prior experience. When I was doing the CCAC work, the pharmacists did pre-checks and calculated all the dosing or whatever else.

I wasn't involved in the process of preparing the calculations for a lot of the mixture breakdowns. Knowing that they weren't patient-specific and that these were pre-existing formulations, they did what they needed to do with giving us the proper dilutions and to make them the product that they were asked to make.

M^{me} France Gélinas: In the other setting that you had worked in before, were you ever preparing medications that were going to be patient-specific?

Ms. Roberta Young: Yes. All of them were.

M^{me} France Gélinas: All of them were? Okay. Would it be, then, within your scope of practice to make sure that what you are preparing is appropriate for a patient?

Ms. Roberta Young: For us at that point? No, it was not our scope of practice to do that.

M^{me} France Gélinas: I'm basically trying to understand within a technologist's scope of practice. Do you have access to information such that when it is appropriate, when you're preparing something that is patient-specific, you would know what dosage is appropriate for a patient? Or you never know?

Ms. Roberta Young: It's not for us to determine if it was the proper concentration. That's what the pharmacist did the pre-checks for. They would determine. They would do all the calculating. They had all the information—the body weight, the testing and whatever background needed to be done for that patient. They would have made that conclusion. There have been instances where a technician, just from experience, has caught the odd thing that we had questioned along the way, but that's not a requirement of us.

M^{me} France Gélinas: I take it that you were in the room—and I'm not too sure who I should ask my question of; I have a feeling it will be the pharmacist. There were conversations that were relayed to us that at some point you saw that the concentration of vancomycin was not appropriate. Somebody called the hospital pharmacist and was more or less told not to ask questions, just to provide the products. Do you know who had that conversation?

Ms. Roberta Young: I do. It was Laura Savatter.

M^{me} France Gélinas: What else do you remember from that conversation?

Ms. Roberta Young: We were asked to provide a higher-than-usual dose of vancomycin. Due to our experience with vancomycin in the patient-specific formulations, we knew that that was a higher dose that had the potential to cause this syndrome. She sent an email regarding that to the pharmacist in, I believe, Thunder Bay. I can clarify that once I look at the email. Not in as harsh words as "It's not your business to ask us," but politely writing back, "We're aware of the situation and, you know, we're asking you to make this. We are taking steps to ensure that we administer it properly to avoid that situation."

M^{me} France Gélinas: Are you aware of other instances where flags—you're noticed that some of your colleagues have picked up flags before when something was being prepared that raised a flag. Are you aware of

other instances where yourself, a technologist, or people you work with kind of picked up on, “Hmm, maybe we’d better check”?”

Ms. Roberta Young: Not really. Only mostly with this product, because all of the other products that we prepare were already established products on the list that was given to us. This was something that was asked for in addition to the existing Medbuy list.

M^{me} France Gélinas: I see. I see. Which is why—

Ms. Roberta Young: It was questioned.

M^{me} France Gélinas: —it raised red flags.

If I was to ask you the same thing, Ms. Salman, in the course of your work as a pharmacist, did you ever pick up red flags that you were about to prepare a medication that is not within a proper dosage?

Ms. Kawther Salman: Do you mean my work with Marchese Hospital Solutions, like IV fluid, an IV fluid? Like now, in Marchese Hospital Solutions, right?

M^{me} France Gélinas: No, in your career as a pharmacist.

Ms. Kawther Salman: In my career, if it is Rexall pharmacy, if I have a patient, I have the prescription. I’ll double-check; even I ask another person with me to double-check everything—the dose, if it is the right administration. We will double-check everything.

But in Marchese Hospital Solutions, no. Because when I started, if you see, they started production in February; I started with them in the middle of July. Everything was ordered by hospitals, and there wasn’t any issue with the production, with the order by hospitals. The breakdown was created. We considered—me and the IV technician—they considered the breakdown as a bible for us. We just follow the breakdown. We don’t have to check it again, because it’s already created by a team of experienced pharmacists.

M^{me} France Gélinas: I’m trying to understand what makes you so confident that, although you have the knowledge and skills to check for dosages that are appropriate for patients, you found yourself in a situation where it was okay not to check. Is it because you really had confidence in the team that had prepared the bible list?

Ms. Kawther Salman: Because I trusted the team, because there wasn’t any issue with the orders, so why I should check? If something is right for me—we are producing these orders on a daily basis, and hospitals are getting these orders since February, and there wasn’t any issue, so why I shouldn’t be confident?

M^{me} France Gélinas: So that gives you the confidence—

Ms. Kawther Salman: Yes.

M^{me} France Gélinas: —to not have a look and to not go any further.

When you had your first telephone conversation with—I take it that it was also with Judy—do you remember how long this conversation lasted?

Ms. Kawther Salman: It’s less than five minutes.

M^{me} France Gélinas: And what was your initial reaction when you realized that they needed the concentration-specific and you hadn’t been doing that?

Ms. Kawther Salman: As I said, I was working in the anteroom and checking, and Bobbi told me they wanted to clarify about the concentration of the admixture that we are preparing. So when I called her, I told her, “This is the way that we are preparing.” She asked me, “Do you remove the overfill from the bag?” I told her no. She said, “So the concentration will not be 38 milligrams per millilitre?” I told her yes, and she said, “So we have a problem with the computer.”

I have no idea how the hospital use, and I have no idea that they will have a problem because their computer, I understood, accepts specific concentration and will not accept the concentration with the overfill. So, at that moment, I just wanted to help her to solve the problem, and I said, “Is it possible to give it as a whole bag, like by gravity?” She said no. At this moment, I realize that they have a problem. She said, “Okay, I’ll speak to the pharmacist in Lakeridge, Oshawa, and I’ll call you back.” Right away, when I finished my call with Judy, I wrote my email. I think you have it.

M^{me} France Gélinas: Right away, you knew the solution was to change the way you were preparing those two products—that product, anyway, to have it concentration-specific?

Ms. Kawther Salman: Yes. Our product doesn’t meet their requirement. Their requirement—they want a concentration-specific solution. Our admixture is concentration-non-specific.

M^{me} France Gélinas: How big of a surprise was it to you?

Ms. Kawther Salman: Sorry; say it again.

M^{me} France Gélinas: Was it a big surprise to you to get that call, to realize that your product was not meeting—

Ms. Kawther Salman: Yes. Yes.

M^{me} France Gélinas: It was a big surprise?

Ms. Kawther Salman: Yes, because we realize the hospital have a problem, so the patient will have a problem. The patient will not get their medication. We address right away to the management team, who can make change, who can make communication.

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M^{me} France Gélinas: Since that phone call, have you ever gone to check what the normal dosage is for those drugs?

Ms. Kawther Salman: After this? Yes.

M^{me} France Gélinas: And what did you find out?

Ms. Kawther Salman: I found that it’s by the surface area and there is no specific dose. It depends on the patient’s weight and height.

M^{me} France Gélinas: Knowing what you know now, are you still willing to say that this bag could have been used for a single patient?

Ms. Kawther Salman: It depends.

M^{me} France Gélinas: Do you figure there’s a single patient that could use four milligrams?

Ms. Kawther Salman: No.

M^{me} France Gélinas: Why do you say that?

Ms. Kawther Salman: Because according to that dose, it’s too much for one patient.

M^{me} France Gélinas: Is it close to a single dose or far away from a single dose?

Ms. Kawther Salman: I cannot say. I don't know, because it depends. We have to calculate the patient's surface area and we calculate how many milligrams the patient will need.

M^{me} France Gélinas: We were told by other pharmacists that we would need to have a standard male who was 5 foot 10, 900 pounds to ever need such a dosage. Do you figure that's accurate?

Ms. Kawther Salman: Sorry, say that again? What was accurate?

M^{me} France Gélinas: When the bags that you were preparing—if they had to be used on a single patient, that patient would have had to weigh 900 pounds.

Ms. Kawther Salman: I think we'd have to make a calculation to find the weight of the patient.

M^{me} France Gélinas: Since this happened, have you looked at the use of this drug at all?

Ms. Kawther Salman: Sorry, have I what?

M^{me} France Gélinas: Since you were coming here today, we were going to talk about those two chemo drugs. Did you look at them at all to see how those drugs were being used?

Ms. Kawther Salman: Yes, for sure. I reviewed the monograph for both of them.

M^{me} France Gélinas: And what can you tell us about them?

Ms. Kawther Salman: It's chemo medication. It can be given alone or in a cocktail with other medication. The dose depends on the patient. We have to get the patient's surface area from the height and the weight of the patient. There are many regimes of chemo medications. There is no specific regime to give this medication.

M^{me} France Gélinas: Okay. I'll hold my time.

The Chair (Mr. Ernie Hardeman): You have about two minutes left.

Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Thank you for coming in. Certainly what you presented to us was very, very clear.

I'll turn to Ms. Salman first. Once you, in particular, understood that Judy at the hospital was having difficulty with the overfill because she required the concentration-specific dose to calculate the correct dose for the individual patient, you came up with a couple of solutions. If you had to produce the admixture in either of the two ways that you suggested, would it have been much more time-consuming? Would it have been a difficult process? Could you describe to us what difference that would have made in terms of the time for preparation?

Ms. Kawther Salman: For the preparation of concentration-specific and non-specific?

Ms. Helena Jaczek: Yes.

Ms. Kawther Salman: It's the same. It's just one step, that we would remove the overfill. It's a bag of 100. Usually the technician, at the same time, withdraws 50 millilitres from this 100 and injects it into the vial of two grams of gemcitabine. And then a second 50 millilitres is

injected in the second vial of two milligrams and shake it to reconstitute. This takes maybe one minute to check the overfill, dispose of it and then, after reconstitution, re-inject.

Ms. Helena Jaczek: So basically a very trivial difference in the process.

Ms. Kawther Salman: Yes.

Ms. Helena Jaczek: I know that we are clear that you weren't involved when the process was decided upon originally by Marchese, but if you had been told it's concentration-specific, it would have been a trivial difference for you to prepare the admixture in that way. It wouldn't have resulted in much more time for personnel—I'm trying to see if this would have had any impact potentially on the price of the bid.

Ms. Kawther Salman: On the price? I don't think so.

Ms. Helena Jaczek: You wouldn't assume so because the—

Ms. Kawther Salman: No.

Ms. Helena Jaczek: And that would be your experience, Ms. Young, as well, that it would have been—

Ms. Roberta Young: Correct, especially with the 100-millilitre bags. There was very minimal overfill in those bags and the syringe would easily remove it with one step, and it would be very little time.

Ms. Helena Jaczek: You both have considerable experience in retail pharmacy and, no doubt, were subject to inspections by the college of pharmacy in terms of the retail—is that correct?—when you were involved in the retail operation, Ms. Salman, as a member of the College of Pharmacists?

Ms. Kawther Salman: So your question is if I was inspected by—

Ms. Helena Jaczek: I'm just saying, were you knowledgeable of the College of Pharmacists' role in retail pharmacy?

Ms. Kawther Salman: Yes. In retail pharmacy, we have to follow the standards mentioned by the OCP, the requirements in the retail pharmacy. To run a retail pharmacy or to work in a retail pharmacy, there is some requirements we have to meet.

Do you want to say about how to run a pharmacy or how to work in a pharmacy, as a community pharmacy, as a staff pharmacist? As a staff pharmacist, I have to have competency that is required by the OCP. I have to have knowledge of pharmacy. I have to be concerned with the patient care, to have direct patient care and to make sure the right medication, the right dose will go to the right patient.

Ms. Helena Jaczek: Were you surprised when you moved to Marchese Hospital Solutions that the College of Pharmacists was not so involved?

Ms. Kawther Salman: Yes, but at the same time, I knew that they are working to get a regulation, either by Health Canada or OCP.

Ms. Helena Jaczek: Who was working—

Ms. Kawther Salman: I don't know the details, but absolutely the management.

Ms. Helena Jaczek: So you understood that Marchese Hospital Solutions was looking for some sort of regulatory oversight?

Ms. Kawther Salman: Yes.

Ms. Helena Jaczek: Do you think that the fact that now the government has introduced some regulations here in Ontario for more oversight—do you think this is a good thing?

Ms. Kawther Salman: Yes. I know that for the OCP, they have a new regulation. It was made into force on May 15, and they agreed on May 10. On May 15, it was published and right away I sent them to Susan James; she's the adviser or practitioner. I told her that I'm working in DPP; the facility that prepared IV fluid they named as DPP. I told her that I am working now in DPP, so I want any form to fill, because they said any pharmacists, according to the new regulation, should be registered with the OCP if they work in DPP and any professional who supervised the preparation of IV admixture should be registered with the OCP.

So right away, on the same day, I sent them an email. I told them I want to register with the OCP. There is a specific form to complete if we need to get a licence to the facility. They said in the law, I have to write the date I started, and I asked them, "Do you want the date before the new regulation or after the regulation?" I also asked them, "Do you want me as a pharmacist to stay in the facility from the beginning"—like, for working hours, because the facility business hours are from, I think, 7 to 5:30, but I work from 8 to 5. I told them, "Is it just the retail pharmacy? You want me to stay there?" Susan told me, "Thank you for your question, your response so quickly. Now we are working on the form that's to be completed. I think she will send me the form to complete this week. I have your name now." I also provided her with the regulated technician who works with me and the part-time or casual pharmacist also to cover me when we need her. She told me that because it's not a retail pharmacy, you don't need to stay all day when the facility is open. You just need to work your hours.

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Ms. Helena Jaczek: So, in summary, you're doing everything you can to ensure that you're doing the right thing by the regulation?

Ms. Kawther Salman: Yes, everything.

Ms. Helena Jaczek: You said you didn't have to provide the name of the pharmacy technician?

Ms. Kawther Salman: No. They ask for any professional who supervises and who checked the IV preparation. Currently, I am the full-time pharmacist, and I also have a regulated technician who has the privilege to check and sign the orders.

Ms. Helena Jaczek: Were you present when Dr. Thiessen came to Marchese? Were you both—

Ms. Kawther Salman: I was there. I was in the checking room. I finished by 5:30. He was there in the last few minutes. I didn't speak to him; I just saw him.

Ms. Helena Jaczek: Ms. Young, were you there, by any chance?

Ms. Roberta Young: Yes.

Ms. Helena Jaczek: Did you find it a useful exchange in terms of discussing the situation as it arose and potential recommendations?

Ms. Roberta Young: Yes, I thought he was very thorough. He asked a lot of questions. He was adamant about gathering all the proper information to make a very informed decision.

Ms. Helena Jaczek: Thank you. We have no further questions.

The Chair (Mr. Ernie Hardeman): Thank you very much. Mrs. Elliott.

Mrs. Christine Elliott: Thank you, Ms. Young and Ms. Salman, for being here today. I just have a few questions of Ms. Salman.

You mentioned that when you started at Marchese Hospital Solutions, you asked a number of questions about what the job entailed and so on. You said that the procedure was already well established by the time you joined.

Ms. Kawther Salman: Yes.

Mrs. Christine Elliott: Did you ask any questions, or did you have an orientation session with people who were already in the department? First of all, did anyone talk to you about what this contract was for and the work you were going to be doing with it?

Ms. Kawther Salman: When I was trained by Stephanie, she trained on narcs order. I asked her what I should—like, you can get help or you can get experience from another one who has experience by asking what things we should concentrate on or what we should look for. I asked her, should I—like, for compatibility, because I worked in Iraq. I was a clinical pharmacist in a children's hospital, and when we prepare or give a patient any medication by IV, the first thing we check is the compatibility. I ask her, "Do I have to check the compatibility?" She said no, because this is all—we took over this contract from another supplier, which has been like for many years, so there is no problem.

Mrs. Christine Elliott: Did you have any conversations with any of the people you were working with about the fact that it wasn't a concentration-specific bag and what it was going to be used for ultimately, and would the people using it know that?

Ms. Kawther Salman: No. But when I started, from the first week I noticed that the weight of the bags is not even. I checked each single bag. I checked the label. I checked is it the right bag, is it saline, is it the right volume. Then I checked the bag to see if there is any foreign object and any precipitation.

I can't tell if there is a difference in the weight, so I said, "What's this difference?" I asked right away. They told me that there is overfill in each bag, which is within an acceptable range. From that, I have the assumption that there is nothing wrong, because it's acceptable; it's within the acceptable.

Always when I have doubts about the weight of the bag, I take it and weigh it. We have a scale which is a calibrated scale. I weigh the bag, and we know—I am not

talking about the chemo; any order—that this bag, before injection, should be within this range. After injection, it should be within this range. We make sure that it is right, it's injected—the right thing, the right volume.

Mrs. Christine Elliott: So you were initially concerned when you noticed that the volume in the bags was different—

Ms. Kawther Salman: Yes. I didn't discuss or ask, "Is it concentration-specific or non-concentration-specific?" But I noticed right away that there is a difference in the weight of the bag. I knew from that moment that there was overfill in the bag, and we don't remove the overfill. It's the contract saying—or, I don't know. That's it. This is the right weight they are doing.

Mrs. Christine Elliott: Okay. But you were told that that wasn't something to worry about; that all you needed—

Ms. Kawther Salman: Yes. It's within the acceptable. There is no problem.

Mrs. Christine Elliott: So you really just checked to make sure that the overfill was within the acceptable range.

Ms. Kawther Salman: Yes.

Mrs. Christine Elliott: Thank you.

Mrs. Jane McKenna: I just have a couple of questions.

The Chair (Mr. Ernie Hardeman): Ms. McKenna.

Mrs. Jane McKenna: Ms. Young, I'm just looking at page 3 here, number 12. You have in here, "I indicated that the bag was not concentration-specific and it was therefore our assumption that it was for single-patient use." The word "assumption" worries me when it has to do with drugs. When you were finished talking with Judy, what did you do after to assure yourself that you weren't assuming that it was a single-patient use?

Ms. Roberta Young: After I spoke with Judy, I immediately went to Kawther to tell her of the concern that the hospital had. It's not my clinical background to know what a dosing of a patient was, and it wasn't in our specificity to inquire about dosing because these were predetermined formulas—recipes per se—that we inherited from the contract. We didn't need to look into that, because this was something that was pre-established. I let Kawther know that they had an issue with the concentration, and she took over from there.

Mrs. Jane McKenna: I guess, Ms. Salman, I'll ask you, then: If someone is on the phone with me talking, and in the second part of that sentence, "our assumption that it was for single-patient use," and then she has passed that over to you, I would want to know if it was or wasn't, because it's not specifically said there. Did Judy get the answer that it was or wasn't for single-patient?

Ms. Kawther Salman: She did not specifically say it's for a single patient. She said, "No, we cannot," because I asked her, "Can it be given as a whole bag by gravity to the patient so you can escape this problem with the computer?" She said, "No, we cannot." That's it. And she said, "Okay, thank you. I'll speak to Oshawa and I'll call you back tomorrow."

Mrs. Jane McKenna: Okay. Knowing what you know now and the outcomes of what you had—and I'm going to ask both of you this question, so I'll ask you, Ms. Salman, first—is there anything in the steps that you have done that you would have done differently?

Ms. Kawther Salman: Can you say it again? Sorry.

Mrs. Jane McKenna: Just because you've been through the process now—and it's like anything: Once you're out of it, you sit there and think, "Gee, maybe I would have thought of that," or "Gee, I would have done this differently." Now that you've had time to digest what exactly has transpired, is there anything you would have done differently?

Ms. Kawther Salman: Yes, for sure. I would make sure about the concentration, about how the hospital will use it, and we would prepare it according to their requirements.

Mrs. Jane McKenna: How would you have done that? What specifically would you have done?

Ms. Kawther Salman: Either by removing the overfill or by using sterile empty bags, and we'd reconstitute each vial of gemcitabine, two grams, with 50 millilitres, and we'd inject it in the empty bag.

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Mrs. Jane McKenna: But who would you have told that to? You just wouldn't have gone and done that without doing anything different. You just wouldn't have done that by yourself, so who—

Ms. Kawther Salman: My responsibility in this facility is—you can say checker or supervisor of production. I will address it to people who can make the decision to change and to do the right thing.

Mrs. Jane McKenna: Now that you're outside of the process, did it seem like an obvious thing to be doing or not an obvious thing to be doing? Is it because of the red flag that people came to you and addressed it? There are a lot of pharmacists that this went through for a year, and nobody picked up on this. I guess we can all say this here, but I'll only speak for myself—there was no time that anybody at any time questioned that until after you were brought to the attention of Judy, who called you to tell you this? Never?

Ms. Kawther Salman: Yes, because for this time no one noticed this problem. If the hospital noticed this problem from the first production, management would probably change the way that we prepared it so we prepared it in the right way. But I think because all this time we did not receive any calls and we did not receive any concerns about the bag concentration, we continued to produce it this way until Judy in Peterborough discovered this.

Mrs. Jane McKenna: Okay. Go ahead, Ms. Young. Is there anything you would have done differently now that you're out of the process?

Ms. Roberta Young: If we were given the same information at the start that we had originally received, I believe we probably would have proceeded in the same direction that we did initially. If it was given to us in a concentration-specific format, we would have proceeded

with the concentration-specific formulation rather than the way that we did do it.

Mrs. Jane McKenna: Okay. Just one more question. I'm only asking all of you this because of the severity of what's going on. There's a lot through this page here—page 4, number 15—when Bert has actually picked up the phone to talk to Ian, and then somehow it goes back to an email exchange. I'm only asking all of you this because I like to phone everybody and then follow up with an email so that the information is correct back and forth. I absolutely dislike emails because—you're already in such a situation right now with what has happened—emails get miscommunicated, and then people think they're reading something when they're not. Do you have a process in place right now where everybody is actually talking? Let me ask you this: Was it ever set anywhere where people were told, "Pick up the phone, talk to the person, and then go back and forth with an email specifically of what you said"? I was just wondering why Bert called Ian, and then somehow it then went to an email exchange. Did he not actually talk to Ian?

Ms. Roberta Young: No. He actually left a voice mail because we did try to do the call first. The call was the first option for us. The voice mail wasn't answered quickly enough; I guess Ian was involved in other things going on that day, but he did respond to his email. The email was the secondary option to try and get hold of him as quickly as possible, which he did reply to and said, "I'm busy. Can you please direct this to Charlene Jones?" I believe that's who it is. Yes. Then I proceeded to call her. She was unavailable at the time. I left a voice mail for her, and she did call me back in the afternoon.

Mrs. Jane McKenna: Okay. That's it for me.

The Chair (Mr. Ernie Hardeman): Thank you. Ms. Gélinas.

M^{me} France Gélinas: I'll go to Mrs. Salman. Do you get calls from hospitals on a regular basis?

Ms. Kawther Salman: Regarding?

M^{me} France Gélinas: Anything.

Ms. Kawther Salman: No, not too much.

M^{me} France Gélinas: Do you ever call hospitals regarding the work you do for them?

Ms. Kawther Salman: No.

M^{me} France Gélinas: No? So there's not much communication there at all?

Ms. Kawther Salman: No.

M^{me} France Gélinas: You know what has happened. You were preparing non-concentration-specific drugs when the hospital needed concentration-specific products. How do you figure that happened? How could it be that you were sure you were preparing the right products, yet it wasn't?

Ms. Kawther Salman: Do you mean how do I can figure out if it's the right thing we are doing or not?

M^{me} France Gélinas: How do you figure it happened? How come?

Ms. Kawther Salman: If there is an issue, like from the hospital, if they have concerns and they call us—they have issues with it—we know there is a problem.

Ms. Roberta Young: I think what she's trying to get at is nobody voiced a concern over this before this initial phone call. We had met the specifications of the contract, and nobody had issues with it before that point. Once the issue had arisen, then we took every step possible to try to rectify that as fast as possible.

M^{me} France Gélinas: Are you still working for Marchese Hospital Solutions?

Ms. Roberta Young: I am, yes.

M^{me} France Gélinas: How about you, Mrs. Salman?

Ms. Kawther Salman: Yes, I do.

M^{me} France Gélinas: How many days a week?

Ms. Kawther Salman: Five days a week, eight to five.

M^{me} France Gélinas: Okay. Thank you.

The Chair (Mr. Ernie Hardeman): With that, we'll go back to the government side.

Ms. Helena Jaczek: No further questions.

The Chair (Mr. Ernie Hardeman): PCs?

Mrs. Christine Elliott: We have nothing further.

The Chair (Mr. Ernie Hardeman): No further questions.

Thank you very much for your presentation. We very much appreciate you taking time out of your busy schedule to be here and help us out with this review. Thank you very much and what do I say? Keep mixing it up.

Ms. Roberta Young: Thank you for the opportunity.

The Chair (Mr. Ernie Hardeman): With that, the committee stands adjourned.

The committee adjourned at 1726.

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Monday 23 September 2013



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Lundi 23 septembre 2013

Standing Committee on
Social Policy

Oversight of pharmaceutical
companies

Comité permanent de
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LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON
SOCIAL POLICYCOMITÉ PERMANENT DE
LA POLITIQUE SOCIALE

Monday 23 September 2013

Lundi 23 septembre 2013

*The committee met at 1404 in committee room 1.*OVERSIGHT OF
PHARMACEUTICAL COMPANIES

The Chair (Mr. Ernie Hardeman): I call the Standing Committee on Social Policy to order for the meeting of Monday, September 23. We're here today to hear depositions on a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies. Dr. Jake Thiessen is here to make a presentation today.

Mrs. Jane McKenna: Point of order.

The Chair (Mr. Ernie Hardeman): Point of order.

Mrs. Jane McKenna: I'd like to do a motion today for the Standing Committee on Social Policy.

I move that the social policy committee support the PC caucus programming motion and proceed with the Local Food Act as programmed in that motion.

The Chair (Mr. Ernie Hardeman): Thank you very much for that motion, and you have every right and ability to table it with the Clerk, but this committee is structured today to hear depositions, and the schedule is full with depositions, so we will not be able to carry on with this motion or debate on the motion in any way. So table it with the Clerk.

Mrs. Jane McKenna: Thank you. I hope we have everyone's support in the House when we do.

The Chair (Mr. Ernie Hardeman): Any further? Okay.

DR. JAKE THIESSEN

The Chair (Mr. Ernie Hardeman): With that, Mr. Thiessen, the floor is yours. I should remind you, you have sworn the oath in your previous appearance, so you will not have to be sworn in again, but you are under oath as you're testifying.

Dr. Jake Thiessen: Thank you. I asked the Clerk—

The Chair (Mr. Ernie Hardeman): He already told you that.

Dr. Jake Thiessen: Yes. He told me that, but then I said I'm delighted to know that I've been under oath for the last several months.

The Chair (Mr. Ernie Hardeman): Yes. He's very thorough and he's not as confident of my abilities as I am, so he thought maybe I might forget.

Mrs. Jane McKenna: Chair, who is asking the questions first? If you said it, I'm sorry; I didn't hear you.

The Chair (Mr. Ernie Hardeman): It will start with the official opposition.

Dr. Jake Thiessen: More formally, good afternoon. Thank you for inviting me to come back. I trust that our time today will be helpful as I share with you the findings of the report and the information that is presented in it.

As you know, this report was delivered on time, may I say, which was July 12, 2013.

Interjection.

Dr. Jake Thiessen: Pardon?

Mr. Rob Leone: That's unusual.

Dr. Jake Thiessen: Well, thank you.

Ms. Helena Jaczek: Not from a health professional, I should say.

Dr. Jake Thiessen: I do come from a family of businesspeople, and I do also engage in this to some degree, so I know: on time, on budget—how important that is.

Interjections.

The Chair (Mr. Ernie Hardeman): I'm happy we're having a mutual admiration society meeting, but if we could just carry on with the appropriate presentation.

Dr. Jake Thiessen: With that, please: In my report to you, I have given this information that I'm going to refer to. I apologize, but I'll probably just read from most of it, although I may interject from time to time.

My opening remarks today will basically be those that I delivered at the time, on August 7, when the formal release of the report was made, at which time I gave these very comments. I also will not present my qualifications again. They were given to you on May 27 and they're also identified in appendix 1 of my review.

Just to help us with the overview, I've broken out the various sections of my report, as you will have it before you, I suspect.

Of course, there's the executive summary on pages 1 to 3.

There's the table of contents, which appears on page 4, so if I suddenly say "this and this," kindly refer to that.

The introduction paves the way; it includes some background information on how I was going to go about it, which is on pages 5 to 9.

The observations from the investigation appear on pages 10 to 22.

The recommendations are launched on page 23, ending on 39.

There's a very crisp, simple conclusion statement on page 40.

There are acknowledgements on page 41.

References appear on page 42.

Lastly, the appendices are on pages 43 to 53.

That gives you a breakdown of my report.

My report presents details regarding the independent investigation of gemcitabine and cyclophosphamide underdosing that affected, as you've all heard by now, 1,202 patients in Ontario and New Brunswick. My investigation schedule is presented in appendix 2, which is on page 44, and you can see the itinerary of various people that I visited.

I chose to begin with the hospitals in both provinces to understand precisely what had happened and why and how they had responded to the crisis. To gain further evidence, I probed what might be considered the primary, directly linked stakeholders. These included the group purchasing organization, namely Medbuy; the vendor, namely Marchese Hospital Solutions; the previous vendor, which was Baxter, which we might say was the incumbent or the historic one that really was the first to engage Medbuy in a contract; and the suppliers of the pharmaceutical materials and the diluents. Just to make sure we all understand, "diluents" is the term we use scientifically simply to identify the material that is used to dissolve the drug that was in the vials.

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The review also took in key professional, structural, regulatory and oversight stakeholders. These included organizations like Cancer Care Ontario, Health Canada, the Ontario College of Pharmacists, the Institute for Safe Medication Practices and the Canadian Society of Hospital Pharmacists. People sometimes wonder, "How far and wide did you go?" Actually, I formally interviewed about 100 individuals in the course of this investigation and informally spoke with many others. I sought to gain factual, substantiated evidence, collect information and determine the viewpoints on a variety of issues that surrounded the incident. Just in case you were not clear about this, this was truly independent. I was the only person working on this.

The major findings were as follows: 1,007 patients were underdosed with cyclophosphamide; 191 with gemcitabine; and four received both oncology medications. The largest fraction, which is 1,162, was adults, and 40 were pediatric cases. All but 30 patients were being treated for cancer—I've given you some information there on page 45 of appendix 3. Just to help a little bit, people often ask me, "Why would anybody get an anti-cancer drug and not be an oncology patient?" I'd say, "Well, in the case of cyclophosphamide, it is very good in knocking back the immune system, and so there were patients with lupus and rheumatoid arthritis who also received cyclophosphamide as part of their treatment."

As far as product preparation, I gave you some of that on May 27. Again, I've distilled the essence of the

comparison in table 2 on page 16. The vendor used only Health Canada-approved materials from registered suppliers. It employed a bulk reconstitution process that used the correct amount of drug and pre-filled saline bags that had some overfill. The overfill, which was furnished to me by Hospira—which is the bags they used—is identified in table 3 on page 18, and you can see what the numbers were in all the lots that were actually used by Marchese in making their dilutions. For example, a bag labelled 100 ml saline—by the way, it says on there, "100 ml bag"; that's what it says on the bag from the supplier. The same thing happens with Baxter; it actually has that on there. So, a 100-millilitre saline by the supplier actually contained, on average, 107 millilitres of the diluent. That would translate into a 7% overfill.

Such overfill led to an excess in the final fluid volume that was not accounted for when the company labelled the product sent to the hospitals. As a synopsis, then, the resulting dilution factor was an average of 7% for gemcitabine and 10% for cyclophosphamide.

Moving on to the group purchasing organization—namely, Medbuy—it is an organization whose members are hospitals. They actually service all of those. They have amalgamated purchasing power, which we've talked to and that I think you've learned about before. They awarded the drug product preparation contract to Marchese on the basis of four objective factors. I've identified those factors on page 21. Of these, the cost of the contracted products only represented 25% of the final evaluation score.

I clarified at the press release that Marchese did not present the lowest price. Nonetheless, in defining the products to be prepared, only a simple statement of specifications was used; namely, the amount of active ingredient per bag of the product—for example, for gemcitabine, 4 grams in 0.9% of the diluent injection bag, 100 millilitres per bag. That's how it was written.

I'm going to interject here, just to help a little bit. When Marchese was considered for this contract, one of the things Medbuy did was investigate what the capabilities of this company were. I can tell you that at that point, which was in 2011 when they made the application, Marchese was producing 752 products. I believe that all of the requested products that Medbuy had, which was 117—I know that number for sure, and I'm not sure if Medbuy was now 118 versus 117, but all of those were identified in the 752 that Marchese had already been producing. I think that's important for you to understand. This wasn't that Marchese was now producing some new things that they hadn't been doing; they had already been doing these kind of things, and they, in fact, had been doing this for gemcitabine and cyclophosphamide.

So the amalgamated outcome, as I'm putting this story together, is the following: The simple statement of specifications led Marchese to use a process that failed to adjust for the overfill volumes.

Finally, the hospitals did not correct their patient-specific doses—because it's an amount that they need per patient—to factor in the overfill, because there was no

clarifying patient-related instructions from Marchese, and the hospitals were therefore unaware of the lower concentrations. This is how patients were underdosed an average of 7% with gemcitabine and 10% with cyclophosphamide.

In this story, there is no evidence of any harmful intent to provide diluted products and thus underdose patients. The problem boiled down to gaps in communication and its unintended consequences. I can tell you, everybody's embarrassed.

What was the impact of the dilution factor on the patients? At this point, the impact is unknown; however, due to the relatively low degree of underdosing, along with the high prevalence of combination oncology drug use, the probability is small that the shortfall had an overall serious effect.

For those of you who wonder, I went through the records of Cancer Care Ontario to find out what the approved programs of treatment were in patients—CCO basically sanctions the treatment protocols—and whenever gemcitabine was used, 74% of the instances of gemcitabine use would be combination. For cyclophosphamide, aside from those immune patients—the ones who were dealing with lupus or rheumatoid arthritis—96% of cyclophosphamide is used in conjunction with other treatments. So it's essentially never alone.

The conclusion, therefore, because of the high problems of combination and the 7% and 10% which I've referred to, is consistent with the clinical decisions made at the affected hospitals, wherein oncologists generally simply continued with their patients' treatments despite this incident.

Lastly, to the recommendations: The recommendations really flow in many ways from the observations, and so in some ways they are best understood if you bring those two together—the observations and the recommendations.

Sorry to remind you about this, but I was asked to try to provide recommendations that would prevent incidents of this nature; for me, this nature meant several things. One is, naturally, in the world of oncology and what one would encounter, but if one looks at this entire structure that exists as part of product development and distribution, there was a broader field that I felt I needed to address simply because of what I had observed and knew. So I fundamentally examined the entire area of sterile and non-sterile product preparation wherever it might occur; that is, licensed pharmacies and other enterprises. I've concluded that there is a need for greater vigilance in order to mitigate identifiable risks. Simply translated, I've sought to heighten the safeguards for patients to impose a higher, more rigid standard around product preparation quality, and to stipulate various checks and balances. In essence, it boils down to three things for me: product quality, patient safety, and checks and balances. Those need to be in place, so I made some fairly sweeping recommendations that are broadly captured by five entities.

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Recommendations 1 to 4 are all about group purchasing organizations, like Medbuy, which must engage in more rigorous risk-based procurement processes and provide greater specificity for drug product preparation services.

Recommendation 5 is directed at the vendor in this case, which is Marchese. They must review their practices and ensure alignment with my various product preparation recommendations. But many of the things for Marchese are also addressed in some of the previous recommendations for the GPO, the group purchasing organization.

Recommendations 6 to 9 and 12 are directed to the Ontario College of Pharmacists, and in many ways they're also directed to the broader regulatory colleges across Canada: that they shall, in conjunction with Health Canada, define objective, recognized standards for sterile and non-sterile drug product preparation within licensed pharmacies. Inspection criteria shall be collaboratively established.

In addition, I'm calling for—and I'm very forward-thinking on what could potentially happen; what I need to make sure is that the patients are protected—electronic records for materials prepared, along with specialized label requirements. We just need to move to areas that some places are using, and it would be a travesty if we didn't close this off.

I'm very firm on requiring credentials beyond education and licensing for personnel engaged in product preparation. To me, just because you have a pharmacy licence and graduate from a pharmacy institution recognized in Canada and are licensed by a college is no guarantee that in fact you know what to do in product preparation, because of the nature of the newer pharmacists that are coming along. I want a specialized designation for pharmacies preparing large volumes of prepared products, and inspection of such will be annual. Of course, I've mentioned the licensing of hospital pharmacies, which hasn't existed to date.

Recommendation 11 is addressed to the Ontario Hospital Association. I want them to review their hospital record systems for traceability and efficiency. We can discuss that further, if you like.

Lastly, I want Health Canada to regulate all drug preparation premises beyond the pharmacies that are licensed and regulated by the provincial colleges of pharmacists. If you have read the report, I'm even saying this: If any pharmacy is shipping medications across a border, I want Health Canada to license that, because in our case we actually had Ontario shipping to New Brunswick, right? If one of the other vendors had been secured, like the Quebec vendor, the product might have been prepared in Quebec and shipped to New Brunswick and Ontario. So you've got to have a way of ensuring that in fact only high-quality products enter the marketplace.

In closing, as I've said in the report, I commend administrators, physicians, pharmacists, nurses and other

personnel in the affected hospitals for their timely and innovative responses. Their actions clearly demonstrate that their primary concern was for patients. These professionals are a credit to our health care system.

Lastly, I wish to acknowledge and recognize in particular the numerous patients and caregivers who faced the emotional impact of this incident. I trust that my efforts in uncovering the cause of the underdosing, in exploring various particulars around this issue, and providing recommendations, will offer a measure of encouragement. May the outcome of this report, this investigation and the things that will follow be a fresh confidence that the future will bring improved safeguards for product preparation throughout the health care community. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation and all your hard work and thoroughness in preparing your report. With that, we will start the questions and comments from the official opposition. Ms. McKenna?

Mrs. Jane McKenna: Thank you so much, Dr. Thiessen, for coming back again. I'm going to reiterate what the Chair said: All your hard work and coming in on time was superior, and I really, really appreciate all that you've done here.

I have two questions. My first question is, because of my recollection of the depositions we have heard from all parties and in the notes prepared by the legislative research service, there was confusion around labelling. We also heard that the Institute for Safe Medication Practices, or ISMP, has identified the need for a national labelling standard. The Ontario Hospital Association has also said that national labelling standards are necessary, and we heard that Cancer Care Ontario's guidelines were not specifically designed for compounding facilities but were intended for individual patients and cancer centres. So could you outline, please, the reason for your recommendation that the National Association of Pharmacy Regulatory Authorities, NAPRA, should develop label requirements?

Dr. Jake Thiessen: Thank you. Yes, label requirements mean different things to people. But what I think ought to be absolutely clear is what's there, for who, how it's to be taken and, in our case, there was another important element, which was the end user. I've identified this in the report as the pharmacists at the hospitals.

There ought to be no uncertainty, absolutely none, about what's in that product—that's one thing—what's in there, what the concentration is, and because many of these people are getting these drugs as infusions, how the infusion pumps are to work with all of this, so that there is no uncertainty about the whole thing. We can fly wonderful jets, but we can't get this right? This doesn't make any sense, you know? We've got to have absolutely solid label requirements in that regard.

The other thing that I've mentioned even in my opening remarks is the whole thing about traceability. I've done everything I can to shore up this entire area. I think I can say that the stakeholders that are part of all of

this are anxious to move this all ahead. Can things that weren't anticipated happen? I suppose the answer is that there's always this possibility. But I want traceability. You should be able to take a barcoded medication and, with an instant and time through your computer system, say, "I know that this patient was on it and I know that there were three times this patient got it." This is inexcusable if we can't do that.

I've been in enough places that I see what goes on. My own pharmacy where I go to has a barcode on it. My medications have barcodes on them, so I'm very satisfied with that. But I've been in hospitals, and I see that they just don't know. I've asked, even in the course of my investigation—I've said, "So you make this stuff in-house now?" Just because you make it in-house doesn't give you any guarantees. It's a closed system; hospitals are closed systems. So you have to make sure that you're not blinded by things like this. But I said, "Okay, so now you've made that. Tell me what's in there." "Well, it's this and this." I said, "Good. Do you know which lot number and which supplier it came from?" They couldn't tell me.

Mrs. Jane McKenna: That's pretty scary.

Dr. Jake Thiessen: This is why I'm saying, labels, electronic records of everything that's there—and it is only then that you can get traceability.

This is long-winded, I'm sorry—

Mrs. Jane McKenna: No, no, it's very good. Thank you.

Dr. Jake Thiessen: —but what we need to do is make sure that there's no doubt about what's in there and what's good for the patient and how to deliver it, and we need to be able to trace everything.

Mrs. Jane McKenna: That's phenomenal. Thank you for all that information. My next question is—that will save so many—clear, concise information of what you're getting there.

The most striking aspect of this committee hearing for me has been the role played by Medbuy and the group purchasing organization or broker to the hospitals. I understand there are efficiencies that come from volume purchasing, but the more players you have involved, the greater the opportunity for errors to occur.

Medbuy assumed that the product would be delivered the same way as Baxter had because the specifications were the same. Marchese didn't interpret them the same way, however. So my question is, I know you recommended improvements in GPO-based processes. Do you think the communications protocols between Medbuy and a new supplier were adequate? Or do you think that they needed to be more specific?

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Dr. Jake Thiessen: As I think I said when I was here in May, this issue of hand-off is exceedingly important. It's not only how a group purchasing organization hands off what has happened with, let's say, the previous vendor to a new vendor, but also how there's an engagement between all the parties. I must say, there were shortcomings with that in this particular case, but there was no

ill intent here. It was just that in the heat of the battle and so on, these things happened.

I have written in a number of things that need to be done, which range from specifying exactly what needs to be in the specification of a product that's being prepared—that includes the materials, how it is being made, what the label is like etc. I've called that they actually do this pre-emptively with the CSHP, the Canadian Society of Hospital Pharmacists, and ISMP, so that there is no uncertainty.

We go back to your first question: There should be no uncertainty, if and when any new contracts arise, depending upon how this all goes out. Even the end user needs to be engaged with all of this in great detail to make sure the patient is getting the right thing.

I hope I've answered your question. I've come down pretty hard on the kinds of things that are required.

Mrs. Jane McKenna: Yes, you have. Thank you very, very much.

The Chair (Mr. Ernie Hardeman): Ms. Forster?

Ms. Cindy Forster: Thank you, Dr. Thiessen, for being here and for all of the hours that you've spent connecting with various stakeholders across the province.

I just want to clarify something that you said. In the report, you talked about how Marchese was already preparing 752 products in a similar way, and those included the two drugs. Can you expand a little bit more on that issue? Who were they preparing them for?

Dr. Jake Thiessen: That is a question that I may need to ask Medbuy about. The point that I was trying to investigate was this: Was this simply a company that was making new products that they had never made before, or was there in fact a history of making products successfully, as far as Medbuy was concerned? This is when Medbuy informed me, yes, they had investigated all of this and that Marchese in fact had been making a variety of products. I learned it was 752. I also learned that essentially all of the products they were asking them to produce had already been made for other clients. Who those clients were, I do not know. That was not part of my investigation.

Ms. Cindy Forster: So you don't know that those were actually being made at their place of business in the same way that they were now being produced for these hospitals? Or was it their actual local pharmacies that were perhaps making chemotherapy drugs for the community of patients?

Dr. Jake Thiessen: I do not know what their intent was, so I'm sorry, I'll need to defer that to others.

Ms. Cindy Forster: Okay. On page 6 of your report, you discuss root cause analysis, and you say it's "designed to answer three basic questions following a critical incident or adverse event in health care: what happened, why it happened, and what can be done to reduce the likelihood of it recurring. However, RCA does not directly address a fourth question"—you spoke to it briefly: "has the risk of future event recurrence actually been reduced?"

Dr. Jake Thiessen: At this point, my report has made a variety of recommendations. The degree to which these recommendations have been implemented, I do not know at this point. I think that they're under way, from the best that I can gather. Therefore, the implementation of them is not yet complete. What I'm suggesting, then, if the intent was to actually eliminate these kinds of errors—I dare say it's going to take several years before we'll know whether there's any recurring incident of this type, based upon the changes that occurred in the system. With all due respect, I think we have to yet wait and see whether the recommendations actually make a change.

Ms. Cindy Forster: So if it is going to actually deal with the issue of reoccurrence with the recommendations that you've made, is this going to include other medication errors or simply just for oncology medications?

Dr. Jake Thiessen: In essence, it's really the broad area of what I call sterile and non-sterile product preparation. So it's not only oncology; it includes all the others as well.

Ms. Cindy Forster: On page 13 of your report, you stated that the Ministry of Health and Long-Term Care "sought to determine what outsourced suppliers were being used by hospitals," and that there was a request to ensure that only suppliers with predetermined qualifications would be servicing the hospitals. Do you know how onerous a process that was?

Dr. Jake Thiessen: It basically sought information through attestations, and I believe the date was April 19 when this was sent out to all the hospitals. In due course, they came back with information that, yes, they were only going to be using—if they hadn't—suppliers that were predetermined to have met the requirements. I understand that, in fact, all of the institutions conformed to the request and provided the assurance.

Ms. Cindy Forster: Do you know why the ministry was not previously collecting this type of information?

Dr. Jake Thiessen: I do not.

Ms. Cindy Forster: Or whether they'll continue to collect it on a go-forward basis?

Dr. Jake Thiessen: The outcome of my report really lies in the hands of the government, so what they do with it, I suppose, is in their hands. I would be surprised if government wasn't as keen to make sure this doesn't happen again as I am. That's the best I can answer.

Ms. Cindy Forster: On page 15 of your report, you state, "It is noteworthy that this stage of dissolving the drug powder in the vials may consume considerable time." We heard that from some of the witnesses along the way. "This is an important reason why outsourcing through vendors is used by the hospitals. In a busy oncology service where many doses are prepared daily for patients, waiting for a drug to dissolve is a substantial inconvenience." Was this something that you heard at the hospitals from pharmacists?

Dr. Jake Thiessen: That's correct. I heard it from pharmacists at hospitals. I wanted to know not only what Marchese had done and what Baxter had done; I wanted to know what was going on in the hospitals at that point,

because they had all reverted to kind of a backup plan of doing it inside. So I said, "How do you actually do it?" And they said, "Typically, we'll take those vials of gemcitabine and cyclophosphamide first thing in the morning. We'll decide, perhaps based upon the schedule that was planned for chemo administration that day, how many of those we will need, and then, early in the morning, when the first person comes in, we add diluent to each one of them and then we try to dissolve them." And I said, "How did you do that?" Well, what would happen is somebody would periodically come by and shake them up again, come back and shake them up again etc. Cyclophosphamide is the hardest to dissolve; gemcitabine is much easier.

You can imagine, when you're administering perhaps hundreds of doses in a particular day, this is really quite an inconvenience, so the idea of outsourcing this, having the products arrive dissolved in bags—and it wasn't just vials; it would be in a bag—was for many of them a great convenience.

Ms. Cindy Forster: When the hospitals appeared before this committee, they kind of contradicted that notion in most of the questions that we asked, that it was too time-consuming to prepare these drugs in-house—it wasn't a monetary or a workload issue. So why are we now hearing a different opinion?

Dr. Jake Thiessen: I guess that was because I asked—and each one of them actually had a series of questions that I posed at each one of the hospitals. I asked, "Why do you outsource this?" And the answer was, "One is the length of time that we sometimes have to engage in preparing the vials." I think that was uniformly mentioned, other than Peterborough, because they only had gemcitabine. The others told me a similar story.

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They identified too that this is also, then—it means extra labour, time, and there were people like technicians or whoever who would do some of these things; so there was a time investment in all of this, where these people could do other things. In the entire economics of all of this, it was viewed as a benefit, whether it was time, manpower, cost. I didn't ever inquire, "Well, what do you estimate the cost of dose preparation to be for these two products, for example?" I didn't go there.

Ms. Cindy Forster: Okay. I think I'm going to pass and save some of my time. Thank you.

The Chair (Mr. Ernie Hardeman): Okay. With that, Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair, and thank you, Dr. Thiessen, for such a comprehensive report. Thank you for the clear language in it and the nice, logical flow. I really enjoyed reading it.

Of course, I know the minister, Deb Matthews, who appointed you to conduct this review, is also extremely pleased with the report—to assure you that we will be introducing legislation this fall that, if passed, will allow the Ontario College of Pharmacists to license hospital pharmacies. I know that, as a committee, this was some-

thing that we had latched on to, and you obviously make that recommendation.

I have a number of areas where I'd like a little bit more clarification, perhaps, of what you actually heard during the course of your review. But first, there's a technical question which continues to intrigue me. The overfill that traditionally was provided in the Baxter formulation, which was adjusted for with a corrected concentration: Once that solution is created, do you not then have further evaporation which would lead to a change in concentration over time, or was there some way of an expiry date that would allow for that?

Dr. Jake Thiessen: I hope I understood clearly. The preparation of the reconstituted product by Baxter, just so that we make sure we speak the same language here, entailed really the same thing everybody did, which was reconstitute in the vials. Then they simply took that and put that solution into an empty bag.

Ms. Helena Jaczek: Yes.

Dr. Jake Thiessen: That meant there was a certain volume there. In the case of gemcitabine, actually, there was a slight volume increase because of the solid material. For some reason, in solution, it actually grew—the volume grew—slightly. I think the increase was something like 5%, so that what was thought to have been 100 millilitres of material was actually 105 and change. So there was a slight growth in all of that.

But to, I hope, address your question head-on, the supply of materials from Baxter, then, to the hospitals typically would be used relatively quickly. Therefore, any kind of fluid movement through the membrane would be inconsequential. So therefore this issue of, can I say, a decrease of volume really wasn't there, because typically, it takes quite some time for the water to pass through that membrane.

Ms. Helena Jaczek: Yes. Okay. I assumed there was a time relationship.

Dr. Jake Thiessen: That's correct.

Ms. Helena Jaczek: Okay. Fine.

In relation to your recommendation, I guess—well, it's somewhat related to summary finding number 4. This is the issue related to the group purchasing organization, in this case Medbuy, and its pharmacy committee. There was a failure to appreciate, potentially, the issue that in fact arose. Were you privy to or did Medbuy share with you the actual conversations that took place in the pharmacy committee in relation to these two products and how the RFP was going out and the requirements? Did they really look at cyclophosphamide and gemcitabine from the perspective of what the concentration is going to be?

Dr. Jake Thiessen: I didn't go to any particular conversations—I understand Medbuy is going to be with you. What I understood from Medbuy is this: They had an executive pharmacy group that had a particular role and they had the various pharmacy representatives of the member organizations, and collectively they became part of a pharmacy committee.

This wasn't, as far as Medbuy was concerned, only a gemcitabine and cyclophosphamide story. In the contract there were about 117 products. So it was a much bigger contract, and I think they were all treated in exactly the same way: There was a one-line description; there was no specification on exactly what was needed for every particular product.

I hope I've answered the question. First, I wasn't privy to any conversations, and I didn't even inquire about that. The second thing is that it wasn't only those two drugs; there was a much larger basket of products.

Ms. Helena Jaczek: Since the release of your report, have you had any feedback from group purchasing organizations, or Medbuy in particular, in reaction to some of your recommendations?

Dr. Jake Thiessen: I've remained sterile.

Laughter.

Dr. Jake Thiessen: Sorry for the quip.

I've remained clean. I've stayed out of this, and I said that, basically, I wanted to be completely released from the obligations of this contract before I would do anything anywhere.

Some of you may know that the Ontario Hospital Association is having a conference at the end of October, and I've been asked to speak at that. So there are some things that are coming. I have been approached, but I've said, "I'm sorry. I can't do anything until the government has released me from this responsibility."

Ms. Helena Jaczek: One of your recommendations relates to the Ontario College of Pharmacists, and you mentioned it today: "credentials beyond education and licensing for personnel engaged in ... product preparation...."

Now, you're making that recommendation to the College of Pharmacists. Would it not be better to ensure that this is part of the undergraduate preparation for pharmacists in general, and wouldn't you have a very persuasive voice with the academic community?

Dr. Jake Thiessen: Well, thank you. You're giving me more credit than perhaps I enjoy—not to make light of it.

The programs of study across our country are defined by the Canadian Council for the Accreditation of Pharmacy Programs. There's a fair bit of, can I say, instruction as to what is to be in a program. There is some latitude, but the entire area of product preparation has fallen by the wayside in most places, because there has been this increasing interest in patient care activities; as you know, things like injections are now available in a pharmacy and so on. That said, I can speak about what happened in Waterloo, because I was involved in that program and we've retained it. But that should not be on the record.

The issue here is that I believe that no matter what you do in life where others are affected, you'd better make sure you have the credentials that support that activity. You can't drive a bus or a truck—whatever it happens to be—with a general licence. You must have special qualifications. The same thing applies in this field. You

need to understand how to do things—when you are not well, whether you should even be engaged in any of this; fume hoods or special facilities; what particles are all about and so on—so that you do the right things knowledgeably and with skill and confidence.

I've come down fairly strongly in saying it is not good enough just to have a licence; you've got to have credentials. I'm not alone in this viewpoint. Certainly, an agency that one might say is self-serving, the Professional Compounding Centers of America, which has a subsidiary in Canada, is very big on providing people with instructions as to how to do this. And there are other programs that are available. I think you must have that. I think the patient ought to be able to go in and have confidence that such-and-such—Jake Thiessen—has got these credentials and he is actually qualified to make these products.

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I've even come on further, as you'll see later on. I've said that when I get a prepared product, not something that's come from a pharmaceutical manufacturer, I think, personally, that there ought to be an identified person, a signature or something that identifies who did it, so that you can check and say, "Yes, it was Jake Thiessen, and yes, he has these credentials." I can be confident.

Ms. Helena Jaczek: Thank you. Recommendation 6 and recommendation 10 refer in some measure to Health Canada, and I presume your sterility is extended to them—you haven't necessarily had any communication—but you certainly do see a role for Health Canada, an expanded role as it relates to compounded products.

Dr. Jake Thiessen: Yes. Thank you. I see it in two areas particularly. One area is to license places to make sure that we have the right kind of facility, people, processes, backup plans, electricity—so many things that are important; it's part of GMP, really. That's one facet.

The other facet is that I feel that Health Canada needs to work with the colleges. If the colleges are going to actually inspect pharmacies around product preparation—it doesn't matter whether it's a small or a large enterprise—there needs to be a uniform standard across Canada for the inspection. I think the standards and the inspection process ought to be common, and who better to do this than Health Canada, which walks into pharmaceutical companies to do that? I hope that helps.

Ms. Helena Jaczek: Yes, it absolutely does. Now, you make quite a point in your report of saying that in reaction to the crisis the health care professionals involved acted expeditiously and appropriately in order to mitigate patient harm and to, obviously, deal with and talk to those patients who were affected. Would you say that the Ministry of Health and Long-Term Care also reacted in an appropriate way when they became aware of the situation?

Dr. Jake Thiessen: To somebody who kind of understands fairly large enterprises, I feel that there was a remarkable attempt to intervene as quickly as possible and, thereby, to try to mitigate any further risk. That ranged from assembling a working group—I was im-

pressed that such a big group could be assembled so quickly and that they could address things. From the very beginning, once I came on, which was after my appointment on April 15, I was able to listen in on what was going on in the working group, and I'll tell you, there were just regular meetings. They were scheduled, everybody came on, and I thought that, in the midst of all the things everybody needs to do, people found time to be there, because this was viewed as an—

Ms. Helena Jaczek: Including the Ministry of Health and Long-Term Care personnel.

Dr. Jake Thiessen: Absolutely. It was the ministry which was orchestrating the working group, right? I just felt that this was actually a wonderful template for how to do things.

Ms. Helena Jaczek: Do I have some time left?

The Chair (Mr. Ernie Hardeman): Yes.

Ms. Helena Jaczek: Dr. Thiessen, we as a group, as you know, had witnesses over a period of time, and we heard from Peterborough fairly well into the process. Of course, we recognized the very timely intervention of the personnel in the pharmacy there, and really acknowledged that, thank heavens, they were so diligent in their approach. I guess, in retrospect, should we not be a little surprised that, perhaps, Windsor and London did not come to the same sort of line of questioning as they did in Peterborough? How do you react to that?

Dr. Jake Thiessen: Well, I think you're absolutely correct. On the one hand it creates a virtuous umbrella over Peterborough because they, in fact, were the ones to discover it, I think to the embarrassment of people in other locations who did not. Yes, they should have. In fact, my report indicates what the hand-off ought to be when it comes to the end user. If people carry through on what I'm saying, there shall be a way that the end-user pharmacists in the hospitals actually get a trial sample to start with that they can check, that they can go back and ask questions about etc.

The intent here is to make sure that in the busyness of life, as happens in these hospitals, you actually have a procedure that you need to follow. It's like an SOP, standing operating practice, as to how in fact you change from one vendor to another one and receive those products. But I'm also suggesting that whenever a new batch comes in, that somebody checks to make sure, "Oh, yes, this is what the label should be. Yes, yes, yes"—it's a checkoff sheet. It's kind of like what happens in industry, part of GMP really; right?

Ms. Helena Jaczek: So an additional quality assurance measure.

Dr. Jake Thiessen: That's exactly right. Thank you. A perfect way of saying it. Quality assurance is job one.

Ms. Helena Jaczek: Okay. Thank you very much.

The Chair (Mr. Ernie Hardeman): Thank you. Official opposition: Ms. McKenna?

Mrs. Jane McKenna: A couple of questions. I think the problems, although not intentional, did demonstrate lack of due diligence with Medbuy. To me, there weren't

enough specifications in the actual contract. Why do you think that was?

Dr. Jake Thiessen: I think that's something that only they can answer. Anything that I say is going to be conjectural. It seemed to have worked with Baxter, and they had seen what was going on with Marchese servicing CCACs or whatever else. The way Marchese identified the product seemed to be the same way that Baxter was identifying it, and putting one plus one together, they got three, and it was kind of left at that.

Mrs. Jane McKenna: Yes, because our interpretation—well, actually, facts in here—that what we saw was that Baxter had done this for years with them and had communication going right to the hospital pharmacy and back with them.

I guess I'm just wondering why that appeared that way, because if the broker is the one that's writing the contract and fully responsible for that—in my own mind I guess that's the answer to it: Why weren't they so specific if they were doing a brand new contract with a brand new company that had come to them that was going to be starting this?

Dr. Jake Thiessen: Well, that's a very good question. They were short-sighted in all of this.

Mrs. Jane McKenna: Sadly.

Dr. Jake Thiessen: I think you've put a very good point on the floor here, which is that Baxter gained its reputation on working directly with pharmacists and pharmacies in hospitals.

Mrs. Jane McKenna: Right.

Dr. Jake Thiessen: Their reputation wasn't built on a vendor—sorry—on an intermediary, a GPO. They had the distinguished reputation.

Mrs. Jane McKenna: My next question following with that is, I think the thing that frustrates me the most is that there are just so many dropped balls along the way. Obviously, it's at the expense of everybody else when you don't have an actual structure of what exactly you're doing. You can tick off checks and balances, on which you've done a phenomenal job of doing for us so this doesn't happen again, so thank you very much.

I don't have a lot of questions because you pretty much answered all that, but I guess my next question to you is: You're the aftermath of what's happened, right? You come in with all these recommendations, but France has mentioned numerous times that since 2001, the government has known about the problems with not regulating. So my question to you is, if you found all these recommendations in the aftermath, and yet maybe not as specific prior to the problems that occurred, do you think the government of Ontario's responsibility—they could have found some of these recommendations prior to having the problem afterwards?

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Dr. Jake Thiessen: A fair question. I guess the structure of our government is fundamentally—as I understand it, there are a lot of policy-related issues. But when it comes right down to servicing any particular area, they delegate—to a hospital association; Cancer Care Ontario;

colleges of medicine, pharmacy, dentistry etc.—and they're trusting that the people that they delegate it to are doing whatever is necessary.

I don't think, personally, with all due respect, that just because you put up a stop sign, you hire a cop. You trust, by and large, that people obey stop signs. It's like that with these agencies. You're trusting. That's why one of my comments in the quote is that there's so much trust that we all embrace in society, and this trust is basically that people are going to do the right thing.

So it's fair to ask the question. I'm not surprised they didn't know, and I'm not surprised that they didn't go after it, because there are so many things the government needs to do.

Mrs. Jane McKenna: It makes me sad that you're saying that. I trust that my husband is going to pick up my son after school. If someone's job description is to oversee exactly what has happened here—that's their job description. That's not a trust level; that's just something that it's part of their mandate to be able to do.

Where does the buck fall? Who is responsible? It's wonderful that you're here in the aftermath, and you've done a phenomenal job, but I just wonder if this has been going on since 2001—and they might not have had everything specifically, because this is obviously a specific case that happened. To me, in the end, the government is ultimately responsible because they are the ones that are making sure that everything goes through.

That's the only point that I wanted to make. Trust, to me, is very different than your job description.

Dr. Jake Thiessen: My litmus test is this: Who could have prevented it? I suppose one could say that government could have prevented it, but government doesn't really function at the level where all of this happened. In attributing any of this to government, I think, with all due respect, it goes beyond the oversight agency; it goes to the people that I feel are ultimately responsible. I could identify various places where it could have been stopped.

Mrs. Jane McKenna: Where?

Dr. Jake Thiessen: Well, obviously, if it hadn't been for the BPSA—it's the procurement act, really, or the requirements around procurement—that there was a successful relationship between Baxter and Medbuy. Do you think that if it hadn't been for the BPSA, that Marchese would have gotten the contract? Well, I don't think so. That's conjectural, because there was a successful relationship. Besides, Marchese wasn't the cheapest or the least costly. One could argue that it could have been stopped right there. It would have never happened.

Where else might it have been stopped? Well, obviously at the level of Medbuy. If they had, in fact, contractually done what I proposed here, with detail, it would have specified the product, and it would have been fine. They all use the same materials, so it's not a question of materials. Nobody was trying to save money by using cheap materials or anything like that.

The third place was at the level of Marchese, obviously—if somehow they had done the right thing. In

my report, I've actually said exactly what they should have done: They should have filled the vials, emptied the rest of the bag and then put the materials back into the bags. That would have solved it, but they would have intuitively had to have done that. That's step number three.

Number four: Everybody should have functioned like Peterborough—somebody should have looked at it and said.

So when I look at it, I'm sorry, I see four participants that are key, and any one of them could have stopped this thing. They're on the ground. Those are the individuals or institutions that are designated to satisfy the best interests of people.

Mrs. Jane McKenna: I'm very grateful for that answer. I guess where I just want to finish off for myself—do I have time still?

The Chair (Mr. Ernie Hardeman): You've got lots of time.

Mrs. Jane McKenna: I guess what I want to say for myself is that ultimately, in the end, I'm not saying that those people weren't—because you're 100% right. You're right in there. You know all that. But if someone has come to me, and my job description is what it is and they've clearly been pointing out that there's a problem and it's been going on since 2001, I think at that point, personally, I would not be looking at everybody else to fix it. I would be trying to figure out what the problem was, because people don't come—it's 2013 now—with the same thing over and over again and you just keep dismissing it and passing it on as everybody else's problem, because there is a hierarchy that has the responsibility of that.

So I'm very grateful for your answer, and I'm not, by any means, not thinking that you're right in what you are saying. I'm just saying that, to me, the buck has to stop somewhere.

Dr. Jake Thiessen: Yes, and I suppose we could say that God created gravity; we've got a problem.

Mrs. Jane McKenna: Well, that's—

Dr. Jake Thiessen: Sorry.

Mrs. Jane McKenna: Okay, that's it for me. Jeff, do you have any questions? I know you just sat down. Do you want to just pass and we'll get our time when we come back?

Mr. Jeff Yurek: Sure. I just want to apologize for being late. I was at the committee next door that we just finished, the tanning bed legislation that's going back to the Legislature.

Welcome again.

Dr. Jake Thiessen: Thank you.

The Chair (Mr. Ernie Hardeman): The third party, Ms. Gélinas.

M^{me} France Gélinas: Chair, how long do I have?

The Chair (Mr. Ernie Hardeman): About 22 minutes.

M^{me} France Gélinas: Thank you.

My first line of questioning will kind of continue what MPP Jaczek had started. Basically, you've just gone through four areas where things could have gone better.

In your report, you talk about how there was a fundamental breakdown in communication. Had the hospital communicated to Medbuy more clearly, had Medbuy said the right thing to Marchese, none of this would have happened. Yet we know that they had an advisory committee of pharmacists that helped Medbuy with that procurement, that contracting out. I find your report is very silent on that. My first line of questioning is, how come the silence on the communication chain?

Dr. Jake Thiessen: Well, I'm not quite certain about "the silence." I felt that I was fairly strong with some of the statements so that, for example, the end user would actually define very clearly what is needed. That was there as one of the recommendations.

As far as the infrastructure that is needed at a GPO in order to make sure that every need of a hospital is supplied—that is, every need in terms of product quality and safety—that can best be answered, obviously, in this case, by the group purchasing organization. I don't need to defend them. I do need to say that they certainly had, as I indicated in your absence, really quite a large collection of pharmacy people from all the member institutions that were, I'd like to think, providing some advice. I do know that they would meet periodically. It wasn't every week, but they would meet periodically. So there was an attempt to gain information that would help Medbuy in making the right kind of decision here, but it boiled down to some details that were not well managed, and that is the essence of it. That's why, as you'll notice in the recommendations that have come down on the issue of specifications—what is the expression? The devil is in the details. Isn't that the expression we sometimes hear?

M^{me} France Gélinas: Yes.

Dr. Jake Thiessen: I'm afraid that without rigid and actually very clear specifications, lots of stuff can go south. Whether you do a renovation or whether you do travelling across the country or wherever, specifications are important. I've said that the future security of the patients in Ontario and elsewhere lies in making sure specifications are really clear.

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M^{me} France Gélinas: So jumping from this, the issue of whether an intravenous drug is concentration-specific or total amount-specific is something so basic to the health care system. Anybody who deals with IV drugs knows the difference between the two. Whether you talk to a pharmacy technician, a pharmacist, the nurses—they all know better. They all know that a drug either needs to be concentration-specific or quantity-specific, and they all know how to deal with this. How could we have a culture where health care professionals put their guard down? How could it be that when it came to London, the first one who saw that this was not concentration-specific did not automatically click on? When you talked to all of those people, what brought in a culture where a health care professional actually put their guard down as to the basics of what their professional responsibilities are?

Dr. Jake Thiessen: A very good question. It was obviously inadequate. I have to go back to the specifications simply because that is where one knows what one has. If you say that it is 100 grams per litre, and you have evidence for that, you have a formulation that actually shows what the weighings are, all those kinds of things—and I've identified this in the report about how the specifications are to be written—then you know what you've got. Short of that, you don't know, and so—

M^{me} France Gélinas: But they had reviewed the labels. They had lots of opportunities. We've heard from Marchese, who had really tried to go back to the hospital and get feedback. And yet none of that worked.

Dr. Jake Thiessen: Sadly. Very sadly. And I completely agree with you: It's a shortcoming in a system, in a culture, and one has to really say that, in many cases, the professionals overlooked something that shouldn't have been overlooked.

M^{me} France Gélinas: And you feel that by putting recommendations towards specifications, this won't happen again?

Dr. Jake Thiessen: Well, I think I've tried as best as possible to intervene in this whole system, at various places, and say, "This is what needs to be done." I've used my best experience and insight into all of this to create an inventory, a checklist of things that need to be there and how it's even developed. That's the best I can do.

M^{me} France Gélinas: When you open up—my colleagues told me that your first recommendations you figure are targeted at Medbuy, but really, the first four recommendations are targeted at hospitals. You have made a series of recommendations that would add oversight to an area that already has a ton of quality assurance on it. You have added, in your recommendation, oversight of a part of Marchese that needed oversight, that had none, but I don't get how the oversight of the GPO has improved. Those things, when I try to follow the administrative structure and the corporate structure of these things, make Alfred Apps and Mazza look like a walk in the park. Their administrative structures are really, to me, meant to distance themselves from the hospitals so that they don't fall under the oversight of the hospital.

So here we are, adding oversight to our hospital—I'm not against it, by the way; I'm all for it—but we're adding oversight to our hospitals that already have lots, and we leave those GPOs at arm's length from our hospitals. They have failed us royally, and we put no oversight in. By your report, you value oversight. You've added it to the hospital, you've added it to Marchese, but to the centre of who failed us in the communications chain, nothing will have changed. You are making suggestions to them, and we have no way of finding out if those suggestions will be carried out. I'm guessing that, in the short term, they will; in three years from now, when they will have forgotten those thousands of people who received diluted chemotherapy, it will be back to what it was before.

There is no oversight of those GPOs. There is nothing in your report that talks about governance, that talks about the corporate structures of those things, to make sure that the oversight is carried over. How come?

Dr. Jake Thiessen: All right. I guess quality assurance, in some ways, is a bottom-up program here rather than a top-down. As I understand it presently, there is no oversight-regulatory agency that governs group purchasing organizations. I think you've raised an interesting point, which is, should there be something that is, in fact, done to oversee all of this? I guess that, in the absence of anything before, as I was working through all of this—there is no infrastructure right now regarding all of this.

However, what I've said is that, at the very least, one needs to know who all the vendors are. I've asked for a listing of all the vendors from every GPO, whether it is a public institution or a private institution that is being serviced. I've called for that, so there will be an openness. In the absence of this sort of large infrastructure, it's the best thing that I could do.

But in many ways, I'm calling for kind of a bottom-up, which is that when it comes right down to it, at the level of the patient, which is where the end user engages product and patient, there needs to be an absolute assurance at that point that those products meet exactly what is required. So, moving back up through the chain, this really in some ways defines everything that needs to happen. Pharmacists ultimately need to have the assurance that the vendor has provided exactly what is needed, and the vendor needs to have assurance that it has filled the specifications of the GPO.

That's the procedure that I have proposed for you here. I'll admit I don't have the infrastructure from the top.

M^{me} France Gélinas: So, it begs the question: Why do we need a GPO?

Dr. Jake Thiessen: Well, I guess this is ultimately a question for the hospitals, because it is their service organization, this GPO. It is something that has been developed by them in order to gain a cost advantage in the purchase of a host of commodities.

M^{me} France Gélinas: Yes, but your report goes way further than this. Your report, in the recommendations as well as in the body of it, says that it is inevitable that it will continue, that they have a role to play, and yet they failed us, and we are still leaving the structure in place. We haven't done any recommendations as to how we can pull them into the quality assurance at either end. What am I missing here?

Dr. Jake Thiessen: We may need a government program to oversee the GPOs.

M^{me} France Gélinas: And why didn't you recommend that?

Dr. Jake Thiessen: Well, I suppose I should have. It was short-sighted on my part.

M^{me} France Gélinas: I'll let it—

Dr. Jake Thiessen: I'm willing to admit that that was something that I did not entertain in this report.

M^{me} France Gélinas: But you saw the role that they play?

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Dr. Jake Thiessen: Yes, absolutely. I saw the role that they play and the advantages that accrue from that—advantages, obviously, from the point of view of the institutions. They see this as an important thing. I can certainly imagine an even expanded role for GPOs for the future. The idea of some kind of an infrastructure—perhaps government infrastructure, even national infrastructure—which would lead to some oversight of GPOs is something that is worth considering.

M^{me} France Gélinas: Thank you. I'll let it go around.

The Chair (Mr. Ernie Hardeman): Thank you. The government side. Ms. Jaczek?

Ms. Helena Jaczek: Thank you, Chair. I'd just like to pick up a little bit on Ms. McKenna's line of questioning.

Since you were, as you've told us, privy to all those conversations with the Ministry of Health and Long-Term Care's working group that they brought together, did you ever hear of any evidence within the ministry that there was some awareness of this regulatory gap, that they'd been aware of it for many years, that it was something that had been talked about since 2001 and had been ignored in some fashion?

Dr. Jake Thiessen: Could you help me here, please, with the regulatory gap? Which one are you referring to? This kind of oversight of GPOs, or are we talking about—

Ms. Helena Jaczek: The one that I believe Ms. McKenna was talking about, in terms of neither Health Canada nor the college of pharmacists were involved in oversight of compounding.

Dr. Jake Thiessen: Yes. Well, I don't want to draw this out unnecessarily, but one of the things that many people perhaps don't appreciate enough is kind of the historical feature. On page 30, I talk a little bit about the whole issue of manufacturing and compounding. If we talk about this regulatory gap, if we really need to call it that, allow me this perspective: The history is that pharmacists really furnished all products for patients, and that goes back to as late as the latter part of the 19th century. I think Eli Lilly was one of the first ones, in 1876, that actually formed a company to begin to produce some of these things. Before that, it was really that all products were actually produced by pharmacists—compounded, okay? So this was considered part of the professional responsibilities of a pharmacist.

That task of providing the products in their final form to patients has eroded and eroded with time, to the point where nowadays it's relatively minor, as I pointed out. This is not the story only in Canada; it's the story in the US.

What has happened, and I've seen this in various places—this is more at the national level, whether it's Health Canada or the Food and Drug Administration—is that because of the fact that there's this professional role that exists in history, and yet the primary agency overseeing medications is a national agency, there's naturally

a kind of careful attempt not to step on each other's toes. Gradually, the national agencies like Health Canada and the FDA have begun to take over more and more of this, but always cautiously, because they view the role of the professional as to be respected. This is not only true in pharmacy; this is true in dentistry and various other places.

What has happened here in this story, really, is that suddenly we see something here where it's almost like a regulatory oversight gap. I've never been enamoured with that concept—I'm sorry—because I've always viewed it in history as just part of the natural ebb and flow of a professional.

Ms. Helena Jaczek: So you would say there was no flagrant neglect on the part of any officials within the Ministry of Health and Long-Term Care in terms of what Ms. McKenna has pointed out and is calling a regulatory gap.

Dr. Jake Thiessen: Yes, I don't see any flagrant—absolutely. I see this as just falling into the accepted customs and practices of both.

Ms. Helena Jaczek: Thank you. I guess to just follow up a little bit on Ms. Gélinas's discussion related to the GPOs, when you're talking a little bit about perhaps the potential for some further oversight—notwithstanding that you didn't particularly recommend it—would you be thinking of this only related to compounded products? Would you see the need for something like that when you're just dealing with a standard compound that comes straight from the manufacturer—it isn't changed in any way? Would you see the need there?

Dr. Jake Thiessen: Well, when it comes from the manufacturer directly to the patient, through the pharmacist or dentist or whoever, then we would say that that's part of the accepted distribution system that Health Canada manages. In terms of these kinds of products, it might be just a little bit different than I proposed at various places where something like Health Canada needs to be involved. The idea, though, that a group purchasing organization needs to be held more accountable by somebody—that's worth exploring.

Ms. Helena Jaczek: In terms of quality assurance—we were talking about this in my first round—you suggested that perhaps when that first admixture arrives, that it be tested to ensure that in fact everything is correct. Would you see any potential—as you know, we just heard about a situation where various diagnostic imaging has been checked and been found to be faulty out of Lakeridge and so on. Would you see any need for quality assurance where another pharmacy comes in and checks that particular product or on a random basis—some sort of cross-pharmacy quality assurance as a check and balance?

Dr. Jake Thiessen: Well, in the various viewpoints that I've either sought or that came to me spontaneously, there was one company that said, "Why don't you recommend enlisting us to actually oversee some of these things?" So there are people, there are businesses that I think are following this entire story to see whether there

is a new opportunity to provide quality assurance that doesn't exist. So I guess time will tell whether some of this will take place.

Ms. Helena Jaczek: Thank you. I'll save whatever I have left.

The Chair (Mr. Ernie Hardeman): Thank you. The official opposition: Mr. Yurek. You have 12 minutes left.

Mr. Jeff Yurek: Thank you very much.

Before I ask you any real questions, just to plug the profession of pharmacy: When something goes wrong, you can always call a pharmacist to come and fix up the problems. I've just got to add that in there.

Dr. Jake Thiessen: Thank you, Mr. Yurek. Whether they're an MPP or not?

Mr. Jeff Yurek: Exactly.

Just going over the infrastructure that isn't in place to oversee the GPOs, do your recommendations give a requirement for Medbuy to introduce their own standard operating procedures or a quality assurance program? Will your recommendations lead to that?

Dr. Jake Thiessen: In essence, that is it, because, as you'll notice in the report, I've recommended that they, in fact, connect with the Canadian Society of Hospital Pharmacists, because they serve the hospital community, and ISMP to make sure that they have the right kind of qualifications and standards there. So in essence, it is basically a definition of the standards that are necessary. I haven't actually specified SOPs formally, but I would like to think that that would be part of it.

Mr. Jeff Yurek: Is there a place in this process that you've undergone where you'll do a review in six months to see what they've done with your recommendations and—

Dr. Jake Thiessen: My wife would say no, but that is not in my hand; that is the hand of others. I have not been engaged on that.

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Mr. Jeff Yurek: You have not been engaged on that. Okay.

That was my concern coming forward that has been raised: There is no oversight of these GPOs—a chance—and you've thrown out some recommendations that possibly could lead to a quality assurance standard operating procedure policy to ensure that this never occurs again. However, beyond this committee reporting this and letting the government do what they should be doing, there's no follow-up to bring the trust back to the person getting that chemo drug product that we have not only implemented changes but we have verified that those changes are ensuring a safe product and there's a safe system now working at the hospital level.

Dr. Jake Thiessen: My mandate was such that—and I've delivered on the things that were requested of the mandate, but in terms of making sure that these things happen, I guess the only assurance I can offer at this point is that, immediately following the press release on August 7, there was a working group call and there was—what I heard, because I'm distinct from it; I can just listen in. But there was a mass assurance that, in fact,

they would carry through on every one of the things that were handed to them. This ranges from Health Canada down through the GPOs and so on. People were going to try to make this all happen.

That's the best I can do, Mr. Yurek, at this point. I do know, just in keeping my ear to the track, that there are things that are ongoing to support what was promised at that point.

Mr. Jeff Yurek: With regards to your process that you underwent, did you find any gaps in communication alone, in general, between Medbuy and front-line health care workers such as your pharmacy technicians and pharmacists? Are they able to access Medbuy at any time with their concerns?

Dr. Jake Thiessen: As far as I know, and I explained this a little bit before, Medbuy uses a system where they enlist the pharmacists from the representative institutions that are part of the Medbuy consortium to actually provide advice at various points in time. So there is certainly that engagement. How successful or unsuccessful that is at this point is difficult to say because I didn't really delve into all of that. But certainly there is a system in place for that.

I think what has happened is that, with the recommendations, there will be a new call for engagement, because you cannot institute these recommendations at the level of the GPO without having a whole lot of pharmacy input.

Mr. Jeff Yurek: Jane, did you want to ask something?

Mrs. Jane McKenna: Yes. I just want to go back to where we were just prior to going around again. Just so I'm clear on what you said, so I'm not saying anything that you haven't, while you were speaking, you said the responsibilities of the province and the federals have eroded over time and it's just become custom and accepted. Is that correct?

Dr. Jake Thiessen: The erosion was related to pharmacy and the fact that over time its preparation of products—what we would call compounding—has eroded from a point in, let's say, the middle 1800s, where they were basically doing absolutely everything, to now, where it's relatively little that they do on a comparative basis. What happened in the course of all of this is that something that was basically a professional jurisdiction—compounding—has increasingly become a national jurisdiction because Health Canada oversees manufacturers. It's kind of the shape of a curve that we can draw in the air about who oversees what. There has been, and I mentioned this before, this kind of respect that Health Canada or our food and drug administration has for the professions which allows them still to kind of oversee things that belong to their jurisdiction, and that's how it's been left. I don't think it's necessarily, with all due respect, a major snafu here regarding regulatory oversight. It represents something that's paved by decades of history and it's just an evolving thing.

Mrs. Jane McKenna: Okay, thank you.

Dr. Jake Thiessen: I'm not sure if I addressed your question right.

Mrs. Jane McKenna: Yes, you have.

The Chair (Mr. Ernie Hardeman): To the third party.

M^{me} France Gélinas: I'll open with something that you don't address much in your report either: the pediatric cases. I was wondering if you had found out more than what you have in your report as to what the outcome was on the dosage in the 30 pediatric cases.

Dr. Jake Thiessen: I have not, and I did not. For me, some of this came subsequent, as I was trying to—there were some uncertainties about total numbers, so I asked for an accounting of all patients. This was really, in some ways, after I had done all the visits. I wanted to get hard evidence because I was challenged by, "Well, you've said this number and these people have said this number," so I wanted to make sure I had the numbers right. I contacted them and I said that I want a full inventory. I want to know who got what, because it wasn't even clear whether some of them got gemcitabine and cyclophosphamide. I wanted to get all the information. That's presented in the appendix, where I've identified—as I said, at the outset, there were 30 individuals—I've just got to make sure I have my numbers correct here—who were in fact receiving cyclophosphamide for purposes of knocking down their immune system, which is 30, correct, in appendix 3. They only received cyclophosphamide. I only learned that later on.

As far as the pediatric cases, I tended to learn that later on as well. There was some smattering of information, because I asked, "What was the spectrum?" They said, "From young to older," but I didn't pursue that at that point. I'm sorry, I can't help you on what happened to the pediatric cases. I don't even know the regimen they were on.

M^{me} France Gélinas: Okay. That's fine.

Dr. Jake Thiessen: I'm sorry.

M^{me} France Gélinas: No, no, it was an aside, as in you mentioned it in your report. We've heard something about the pediatric cases, but not a whole lot. So I guess we will leave it at that.

I want to come back to comments that we have heard, where, after Marchese got the contract, they really tried to connect on a number of occasions with the pharmacy staff in the hospitals. It started with London because London was the first one. Although, from what we hear, when London needed to connect with Marchese, Marchese would comply; when Marchese needed to connect back with the end user, the doors were not open for them to do that. From your knowledge of the business, why did that happen?

Dr. Jake Thiessen: I cannot answer that; I'm sorry. I don't know the details of such problems, if they existed. I did ask, when I was at the hospitals, "Did you contact Medbuy or Marchese about this discovery?" and they said yes, that they had. So I knew there was communication. It was intriguing, I felt, that they would go to both Medbuy and Marchese to try to get answers to things. I

would like to think that in the infrastructure that exists around this there would have been clear lines of communication around such issues. They nonetheless did contact them, but the degree to which, the difficulty that you were alluding to, I do not know that.

M^{me} France G  linas: Did they share that with you? Did you know that before you came here?

Dr. Jake Thiessen: That I came—

M^{me} France G  linas: Before you and I had this conversation, had you been made aware?

Dr. Jake Thiessen: When I was at the hospitals, I said, “Did you contact Marchese?” and they said yes. I asked did they get any responses and they said they had some difficulties with the responses, but that was on the discovery of the incident. That was the extent of the communication I had with them over that.

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M^{me} France G  linas: Because when you identified the four areas where—

Dr. Jake Thiessen: It could have been, yes.

M^{me} France G  linas: —things could have been caught—in the recommendations that you made in your report toward specification, and the first batch will be tested by the pharmacists is one of the recommendations that you made—those are pretty basic principles that apply in health care all the time. Why is it that it didn’t come to them without you having to put it on paper?

Dr. Jake Thiessen: Good question. Short-sightedness, too busy, maybe not caring enough.

M^{me} France G  linas: All of the above?

Dr. Jake Thiessen: All of the above.

M^{me} France G  linas: This is a little bit—

Dr. Jake Thiessen: I can’t answer for them.

M^{me} France G  linas: No.

Dr. Jake Thiessen: At best, it’s conjecture. But I said near the beginning somewhere that I think everybody’s embarrassed by this whole thing, embarrassed to the point of, in some cases, very despondent about why this happened and how it happened and who is responsible, and would love to rerun the tape and fix this up, but unfortunately, it happened.

M^{me} France G  linas: Yes, it did. When you were talking, when you had your meeting with the pharmacy staff and the staff from the hospital—you gave us all of the information on those different meetings—I’m guessing: What was the tone of it? You started to talk about this. Do they realize that they could have caught that?

Dr. Jake Thiessen: They’re very embarrassed. That’s why I said moments ago that that is a reflection on individuals and institutions. When it comes to institutions, it’s individuals, ultimately.

I obviously feel for them as well about what happened. If it was one of my sons or daughters as a pharmacist in those locations and had been responsible—I can imagine how people feel. They were devastated by this.

M^{me} France G  linas: Go ahead.

Ms. Cindy Forster: Just one question: When we had Marchese Hospital Solutions here over, I think, two dif-

ferent periods, we asked each of the pharmacists who appeared before us about their experience around chemotherapy admixture-type programs, and none of them really had any, if a very small amount of, experience with chemotherapy agents. But you don’t address that part in your report. Do you have any comments on that? I know you talked earlier about people having credentials as opposed to just licensing, but if you wouldn’t mind speaking to that.

Dr. Jake Thiessen: Okay. The question you’re asking, if I can translate, is: Should the vendor who is doing drug preparation have personnel who have experience in every therapeutic category?

Ms. Cindy Forster: Should the vendor and should the middleman—the GPO—perhaps make that one of the criteria?

Dr. Jake Thiessen: Okay. I would personally not be prepared to go there, and I’ll tell you why. It’s because, if you look at the array of products that are there, they range from what we would consider relatively low-risk to high-risk products in just a host of areas, from antibiotics through epidurals to TPN, chemo etc.

If the specification were that the one giving oversight at the level of the vendor had to have personal experience in each one of the areas, you wouldn’t find people like that, or you would have to have so many employees that you couldn’t afford to do any of this.

I think, when it comes right down to it, drug product preparation is fairly generic. My personal view is it doesn’t require specialization in every one of the therapeutic categories in order to be successful and robust in delivering the required kinds of products. I think you have to be absolutely knowledgeable and experienced in product production, so that whatever the ticket says for the production is what you produce. That’s GMP, good manufacturing practice. I don’t want to toot my horn here, but that’s why I’ve said it isn’t adequate to have a pharmacy licence and be registered with the college. My personal view is that you have to have credentials in those areas, for the good of patients and the quality products that you—

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes their time.

We’ll now go back to the government: Ms. Jaczek.

Ms. Helena Jaczek: Dr. Thiessen, obviously our focus is on looking forward and implementing your recommendations. I wonder if you could just lead us through how you see, in the future, a group purchasing organization putting out their requirements in terms of concentration and perhaps use of cyclophosphamide. And lead me through what you see as the ideal process in terms of obtaining that compounded product. In other words, who should be involved in the discussions? To what extent is the entire process of the compounding gone into? Could you lead me through how you envisage this? Also, scoring, the evaluation criteria—you’ve mentioned experience. Could you just go through some of that so that I have a really clear picture?

Dr. Jake Thiessen: When it comes to the entire matter of a product, the requirements are defined by, usually, a combination of medicine and pharmacy, ultimately. The dose that is requested is a decision that is made, typically, by medicine for a particular patient. Once you have the dose defined and you have the end user who is actually helping to deliver the dose to the patient—that's the role of the pharmacist, typically. Between the two of them, one can define what the dose is, how it's to be administered to patients, if it's in fact in a diluted state, as we talked about briefly before. That defines what the characteristics must be of the arrived product.

As far as the vendor is concerned, that vendor now knows what the expectations are for the arrived product. However, the way this entire system works, it all works through a GPO. In many ways, it is the GPO's responsibility, ultimately, to define the specifications very clearly. That GPO can't do that using individuals who, dare I say, have non-professional qualifications. They must be professionals, because it is the professionals that can best translate either the physician's orders or the product specifications to a GPO, who then passes it off to the vendor. That's the flow that is required.

In terms of the requirements around the way that a vendor actually produces it, there are things that need to be embraced, which I've indicated. It doesn't matter whether the vendor is a pharmacist who is actually producing it or an organization like Marchese that does it on a grand scale. There need to be specifications on how that is being produced. This is why I've been fairly adamant, in my report, that the agencies that oversee this must ensure a higher level of quality specification—I'm going to add the word "specification"—by embracing such a thing as USP 795 or 797, because these things are pretty clear when it comes to what is expected. That's our best standard.

By the way, the Canadian Society of Hospital Pharmacists has been working on a draft of all of this already. This was in the works. So there are things coming. They're going to be working with Health Canada to actually bring this forward. I was made aware of that. Okay?

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There's this flow that begins at the level of interest of the patients, works through product specifications in light of that, and while that's the instruction to the vendor, ultimately, because of the system here, that needs to be appropriately transcribed by the GPO to the vendor so that there is no miscommunication, no shortage of instructions. Maybe what it requires is, as has been suggested, that there be a national organization that oversees GPOs to make sure it really happens.

Ms. Helena Jaczek: So in terms of evaluation criteria, when the response to the RFP is examined by the GPO, what would you recommend as the evaluation criteria for these types of compounds?

Dr. Jake Thiessen: What I've suggested is that there in fact be—first of all, products shouldn't all be in one bucket, as it were, all considered equally. So I proposed

that there actually be an assignment of a risk to a product that is being prepared. This is actually laid out very well in USP 797: what kind of risks are identifiable, whether it's low, medium or high. There are many factors that determine that. We don't have time to go into that, but that's where I think that needs to be done so that when an RFP is now issued, everybody knows that these and these products are in such a category, and there might be three categories potentially. Somebody who is going to be involved in preparation of high-risk materials—my view is that there be special criteria to allow such a manufacturer to actually deliver on those. I should call it a "vendor." I'm sorry: special requirements from a vendor who delivers on those.

Ms. Helena Jaczek: That would include their experience in providing this product previously or—

Dr. Jake Thiessen: Or they do a trial run. There are always things like beta versions. We know that in the software industry. There can be a way of testing them to find out whether they'd do the right job.

Ms. Helena Jaczek: Thank you.

The Chair (Mr. Ernie Hardeman): Okay, thank you very much. We have five minutes left for the official opposition.

Mr. Jeff Yurek: Thank you, Chair.

Dr. Thiessen, the CCACs currently have a system where they RFP out pharmacy services, and the end results of course are different. Off the top of your head, or maybe you've sought it out, is there oversight of the CCACs on this RFP process at all?

Dr. Jake Thiessen: There are requirements. Mr. Yurek, there are requirements. Is there oversight on the CCACs? I'm sorry, I can't answer that.

Mr. Jeff Yurek: I'm just trying to put this together because, right now, we're moving into—your requirements, hopefully, will not end up beside Dr. Drummond's report on a shelf somewhere, but they'll get implemented. But I'm hoping—after they're recommended, now we're finding out that it looks like there's still going to be an area that we need to look at to ensure that these organizations like Medbuy are performing to our qualities that we expect of them.

CCACs have been doing this for a while. I know they have their own committees; all the CCACs get together and they try to make the best possible process available. The LHIN directs some funding to the CCACs, and the LHIN directs some funding to the hospitals.

I'm just wondering if it's already invented somewhere else there of what's going on. Maybe it's going to fall back into the lap of the Minister of Health and her ministry to actually be the overseer of this itself instead of looking at some other national structure or using what we have in place. Your thoughts on what's available?

Dr. Jake Thiessen: Well, thank you. Again, my understanding with these GPOs is, they do not function only in one province. We saw that in this particular case. If we leave this in the hands of a province, I'm not sure whether that's the necessary safeguard. It's only a ques-

tion in view of the things that you came forward with, suggesting about the oversight.

I wonder whether what we need is national oversight on all of this. As surfaced in this particular case, the products flowed from Ontario to New Brunswick. So my concern in all of this for the well-being of Canadians—not Ontarians; Canadians—is that in fact what we are dealing with here is something that safeguards the interests, no matter where you are in this land and no matter how the products move.

Therefore, if a GPO is instrumental in allowing vendors to distribute products across the country, would it be wise to think about a national organization that oversees this—again, to safeguard everybody?

Mr. Jeff Yurek: Okay. Thanks for everything you've done.

Dr. Jake Thiessen: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. You held up very well under some gruelling questions. Thank you very much, Doctor, for being here this afternoon. I think your presentation has enlightened the committee considerably, and we very much appreciate that and all the work that you've done to bring the matter this far forward. Thank you very much.

We'll just hold on a minute. I believe our next deputation is out in the hallway, so we'll just wait for a moment while they come in.

Okay, we shall proceed with the meeting.

MEDBUY

The Chair (Mr. Ernie Hardeman): We want to thank our guests from Medbuy, who are going to make a presentation over the next while.

I understand that of the four people in the panel, there are two that have been sworn in and two that haven't. I just want to remind those that have been sworn in that you are still sworn in, and we'd ask the Clerk to swear in the other two, just in case you have something to say. Thank you.

The Clerk of the Committee (Mr. William Short): Ms. Kelterborn, I'll do you first. Did you want to be affirmed or swear an oath?

Ms. Ann Kelterborn: I'll swear an oath.

The Clerk of the Committee (Mr. William Short): If you'd just put your hand on the Bible, please. Thank you.

Ms. Kelterborn, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Ann Kelterborn: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

Mr. Swartz? The Bible as well? Okay. Thank you.

Mr. Swartz, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. Ron Swartz: I do.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Very good. Thank you very much. With that, we will turn the floor over to you, after a giant thank you for being here. We'll turn it over to you for your presentation, and then we will have questions. The available time will be split evenly between the three parties. In this deputation, we will start with the third party for the questioning.

With that, the floor is yours.

Mr. Kent Nicholson: Great. Thank you.

I believe our opening statement has been distributed, so I'll encourage you to read along with me.

I will start this afternoon by reintroducing myself and my colleague Michael Blanchard and by introducing two new team members from Medbuy who are here to assist the committee today.

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I am, as many of you will remember, Kent Nicholson, the president and chief executive officer of Medbuy. With me today is Michael Blanchard, who also attended with me on May 6, 2013, when we first appeared before this committee. Michael is our vice-president of pharmacy, clinical services and business development. He is a licensed pharmacist who joined Medbuy in February 2013.

Now let me introduce the two new members of our panel. Firstly, Ann Kelterborn is our director of strategic sourcing and member services, pharmacy, with Medbuy. Ann has 30 years of pharmacy experience, having worked in hospital, retail, industry and GPO settings. She is a licensed pharmacist and also received her MBA in 1995.

Also with us today is Ron Swartz. Ron is the manager, clinical services and patient safety, pharmacy, with Medbuy. He's a graduate of the faculty of pharmacy at the University of Toronto and has spent his entire career, prior to joining Medbuy in 2005, in a hospital pharmacy setting. He has worked in large and small community hospitals as the director of pharmacy and in a pediatric teaching hospital. He has a wide array of clinical experience, including pediatrics, pain management, palliative care and infectious diseases.

Recognizing that it has been some time since our first appearance, we thought it would be helpful to reiterate some background on Medbuy and the work that we do.

Medbuy is a national health care group-purchasing organization that works on behalf of publicly funded and accountable health care organizations in Canada. These health care organizations comprise the Medbuy membership, or members, and are also shareholders of Medbuy.

Medbuy has been in existence since 1989. As a GPO, we aggregate the purchasing power of our members to obtain the best value from suppliers for a wide range of medical supplies and pharmaceuticals. The nature of the work that we do tends to drive a higher level of standardization by the hospitals, reducing costs and product

variation. Patient safety and product quality are always a focus of our work.

We bring together clinical experts from among our members who work with our staff to make determinations regarding the products and services that members ultimately purchase. Our expert member committees are actively engaged and participate in all aspects of our sourcing initiatives.

Specific to our pharmacy committee, the committee is comprised of senior licensed pharmacists from our member hospitals.

Medbuy operates like a not-for-profit in that we do not retain earnings. Any revenue that we generate is distributed to our member hospitals in proportion to their spend under Medbuy contracts. In 2012, member spend against Medbuy contracts totalled \$627 million. Since our inception in 1989, we have saved our member hospitals hundreds of millions of dollars that have been redirected to provide front-line patient care.

Prior to this incident, we had a flawless record of providing on-spec products from approved suppliers to our member hospitals.

We welcome the opportunity to appear today as this will provide us with the chance to update the committee on certain developments that have occurred since we were last here, including the report that was released by Dr. Jake Thiessen in July.

The three specific areas that we'd like to address today are as follows: first of all, the regulatory environment; secondly, Medbuy's response to the recommendations of Dr. Thiessen; and lastly, the actions taken by Medbuy in connection with the existing Marchese contract.

Starting with the regulatory environment: As we discussed when we were before the committee on May 6, compounding and admixing by third parties is a service available to hospitals in Ontario for nearly three decades. It's well known both by industry participants and by regulators that this was an activity that did not directly fall within the jurisdiction of either Health Canada or the College of Pharmacists.

We fully support a higher degree of oversight, regulation and licensing. As we indicated previously, Medbuy's awareness of this lack of direct regulatory oversight for this particular activity led us to include certain steps or precautions in our RFP. This included requiring the activities to be carried out under the supervision of a licensed pharmacist and referencing the need that the third party compounder adhere to the USP 797 standard, which is considered the pharmacy gold standard for carrying out these activities.

Since Medbuy's RFP was conducted in the fall of 2011 and, indeed, even since we appeared before this committee on May 6, there have been some important changes in the regulatory environment that will have a bearing on the provision of compounding and admixing services by a third party, whether provided directly to a hospital or through a GPO such as Medbuy. These changes are as follows:

Firstly, there have been amendments made to regulation 965 under the Public Hospitals Act to now include directives to hospitals about the types of organizations—and the requirements those organizations must meet—which may supply products such as these to public hospitals.

Secondly, amendments have been made to the Pharmacy Act to now introduce the concept of a drug preparation premises or DPP, and there is now a requirement that a third party carrying on compounding and admixing services must have a DPP licence such that it will fall under the regulatory oversight of the Ontario College of Pharmacists, which will in turn provide the college with the ability to conduct inspections.

Thirdly, Health Canada has recently taken the position that third party providers of compounding and admixing services must obtain a narcotics dealer's licence under the Controlled Drugs and Substances Act. We are specifically aware that Health Canada has taken this position in relation to Marchese and that Marchese has in fact obtained such a licence.

Fourthly, the province has indicated that it will introduce legislation in the fall to address Dr. Thiessen's recommendation 12, which states, "The OCP shall license all pharmacies operating within Ontario's clinics or hospitals."

For future initiatives, Medbuy's RFP documents will clearly make compliance to these new federal and provincial regulations, where applicable, a mandatory requirement.

Turning to our response to the recommendations in Dr. Thiessen's report: As the committee is aware, Dr. Jake Thiessen was commissioned by the Ontario Ministry of Health and Long-Term Care to conduct an investigation into the oncology underdosing incident and to provide recommendations about how similar events or incidents could be avoided in the future. Dr. Thiessen completed his work and delivered his report in July of this year.

Medbuy completely supports all of his recommendations and specifically those that relate to GPOs such as Medbuy. I'd like to take this opportunity to advise the committee of what Medbuy has already started to do in order to implement the recommendations of Dr. Thiessen that pertain to GPOs.

First of all, recommendation 1—and these are direct quotes and lifts from his report:

"Notwithstanding the underdosing incident, the continued use of group purchasing organizations (GPOs) to negotiate vendor product preparation pharmaceutical services shall not be discouraged. However, improvements are needed in the GPO-based processes."

Medbuy is absolutely committed to continuous quality improvement and has in fact hired a consultant as an independent process expert to undertake a broad review of all of our contracting processes to identify specific ways in which they can be improved. In addition, Medbuy, in conjunction with the members of its pharmacy committee, has created a pharmacy subcommittee to

conduct an assessment specific to the contracting process for the sterile preparation compounding service. To supplement the subcommittee's expertise and to provide a degree of impartiality, we have engaged an expert consultant from the Institute for Safe Medication Practices to work with us through this review.

Recommendation 2: "Every GPO shall review its procurement process to ensure that risk for patients is considered an essential evaluation and adjudication criterion when considering proposals."

As we indicated in our testimony before this committee on May 6, Medbuy has always recognized our contribution to patient safety and care. In order to strengthen our existing risk management processes, we are now introducing enhanced risk assessment tools and mitigation strategies. We have begun our improvement efforts by risk rating every initiative and every product within each initiative that we plan to tender to assist in the development of the sourcing strategy. Risk rating means that you treat high-risk products—which would include chemotherapy medications—differently and apply an even greater degree of diligence to sourcing, procurement, delivery and education in relation to those products. Further enhancements may also come from the pharmacy subcommittee review and from other stakeholder groups.

Recommendation 3 stated: "Every GPO shall develop and adopt a standardized product and/or service specification description that outlines the requirements for contracted sterile or non-sterile pharmaceutical preparation services."

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Medbuy is committed to working collaboratively with all stakeholders, including our pharmacy committee members, the Institute for Safe Medication Practices and the Canadian Society of Hospital Pharmacists, to develop standardized product and service specifications for contracted sterile and non-sterile pharmaceutical preparations. In the interim, as part of our current contract remediation process, Medbuy's pharmacy team, with the assistance of the pharmacy committee, has reviewed the current contract specifications, has prescribed clarification of compounding procedures related to end-user requirements and has ensured that all labels represent the final products precisely.

Finally, recommendation 4: "Annually in January, each GPO shall publicize information regarding the contracted pharmaceutical services provided by all its vendors."

Medbuy will comply with this recommendation, and in fact, this information is currently available. The Medbuy contract with Marchese is the only contract for pharmacy service that Medbuy currently has.

Thirdly, I'd like to transition to a short discussion around the actions we've taken in connection to the existing Marchese contract. Since the discovery in March of this year of the chemotherapy underdosing incident, Medbuy has requested Marchese to make certain changes to their practices that are required in order to ensure this

type of incident is not repeated. Those changes include: To ensure that end-user requirements are understood and met, Marchese has undertaken to review with each participating hospital the compounding formula and label requirements for each item supplied. Marchese will obtain sign-off from the hospital attesting that the items supplied meet their requirements.

Secondly, specific to chemotherapy products, all hospitals have moved this activity in-house. With no further demand for these products, our plans are to remove them from the contract. Should demand for these products appear at some point in the future, the sign-off process that I described above will be utilized.

Thirdly, specific to narcotic products, the requirement that these products be concentration-specific has been reinforced. An improvement implemented by Marchese in August, as a result of our discussions, is the use of sterile empty bags instead of pre-filled commercial bags in the preparation of narcotic items.

Lastly, in the case of antimicrobial products, the use of commercially filled bags has been accepted. Labels for these products must contain the name and total amount of active ingredient in the bag and designate it is a single-dose bag and the nominal volume of the bag expressed as a range.

We feel confident that these improvements in the practices of Marchese under the terms of the current contract will address and remediate any factors that contributed to the underdosing incident that arose earlier this year.

The current contract expires December 31, 2013. At the present time, we have not made a decision regarding a future contract for compounding services. Consideration will include identifying the needs of our membership as well as changes in the regulatory environment.

In conclusion, we have spent a great deal of time reflecting on what went wrong in this situation. What is now apparent to us is that all stakeholders involved in this incident relied on assumptions. Some of these assumptions ultimately proved to be incorrect. The actions that we've highlighted, both related to responding to Dr. Thiessen's report and in remediating the existing contract, are focused on detailing facts and removing any reliance on assumptions or interpretations.

We remain deeply aware of the impact this incident has had on patients and their families. To them we again express our sympathies and pledge our commitment to do everything we can to avoid a reoccurrence of such an incident.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. We will have about 35 minutes per caucus for the questions, and we will start again with the third party. Ms. Gélinas.

M^{me} France Gélinas: Welcome back to Queen's Park. I will start with some of the information that you shared with us in your opening and that is still not clear to me.

The corporate structure of Medbuy: You act like a not-for-profit but you are not, under the law, a not-for-profit corporation. What exactly are you?

Mr. Kent Nicholson: We are a corporation, but the intention in describing our operating model was to be clear that we generate no profits. Any profit or any revenue that is in excess of our operating expenses is returned to our membership 100%. We, in fact, operate similar to a co-operative, if that helps people understand the nature of the work that we do.

M^{me} France Gélinas: What would keep a hospital purchasing department from doing the exact same thing you are doing for a number of hospitals in and out of province? The purchasing department at UHN is huge. They could get deals similar to what you're getting by purchasing for a number of hospitals. What's the difference?

Mr. Kent Nicholson: I'm not sure there's any particular difference, other than the fact that we already exist; we already have the infrastructure and we already have the knowledge base.

I think I shared with the committee the first time I was here that we're not a large team; we're 50 or 60 people. Roughly 20% of our team are licensed health care practitioners: we have registered nurses; we have a physician on staff; we have licensed pharmacists; we have pharmacist technicians.

We started from very humble beginnings. We were three hospitals in 1989, and it was a simple concept: that they had similar needs. The ability to aggregate their volume would tend to get attention in the marketplace, drive better pricing, and that continued for a significant period of time.

Our membership has grown now to include about 25 full members and probably 75 hospitals, so some of our members represent more than a single facility. We continue to aggregate volume and generate savings in taking that to market.

But additional to that, we help foster the ability to drive standardization, so it's really in the way that we work. We have our committees—and I think the first time I was here, I also described our committee structure. We have four committees, and the pharmacy committee is one of those committees. Every one of our member hospitals has a representative on our pharmacy committee. We work in a uniquely collaborative fashion.

We very much are, I think, an extension of our hospitals. We're an extension of the purchasing departments of the hospitals. There's a clear delineation for things that they are buying in common. They tend to rely on our process and expertise for things that are unique to the hospital, and there are hundreds or thousands of those items. Their purchasing department is working hard to kind of keep ahead of the BPS requirements of all of their purchasing activities.

M^{me} France Gélinas: I'm sure you've read Dr. Thiesen's report, like we all have.

Mr. Kent Nicholson: Yes, we have.

M^{me} France Gélinas: He puts a lot of emphasis on oversight. He makes recommendations that the pharmacies in hospitals—although hospitals are heavily regulated and have many layers of oversight, he has added a

level of oversight. He looked at Marchese and basically did the same thing: He said that we have to put in place oversight, and this has been put in place through the college etc. But because of your structure, you don't fall under the many layers of oversight that appear for the hospitals, and here you are with no oversight. Any comments about that?

Mr. Kent Nicholson: I'd make a couple of comments. Certainly we don't operate under direct oversight, but we have regulations that we're under an obligation to follow, the Broader Public Sector Accountability Act being one of those in terms of how we run our initiatives.

M^{me} France Gélinas: Which Dr. Thiessen identified as one of the problems that led to where we're at now.

Mr. Kent Nicholson: We are fully transparent with our membership, so our membership has the opportunity at any point in time to review any of the work that we do. That's not necessarily a common practice, but we have had a hospital member's internal audit department request a review of a number of contracts of ours to assess compliance and understand the process, which we were happy to carry out, and the hospital was very pleased with the outcome of the exercise.

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More broadly, would we take issue or exception with oversight? I don't think we can talk out of both sides of our mouths. I was clear in my opening statements that a number of areas of oversight, be they in a hospital setting or be they in the compounding environment with third parties—I have no objection to the work that we do coming under some oversight. I'm not quite sure what that would look like, who would do that or how that would manifest itself, recognizing that we have membership that crosses the provincial boundary. But, again, we are a fully transparent organization, and I would have no issue or objection to some form of oversight that we would come under.

M^{me} France Gélinas: You have made a number of comments about things that have changed. You made reference to the changes to the Public Hospitals Act, to the Pharmacy Act, to the narcotic dealers' licences, and the fourth one is what will be coming regarding the college looking after hospital pharmacies. But this is not where the problem arose. All of this could have been in place, but we still would have ended up with a failure in communication as to what was needed.

Mr. Kent Nicholson: I'm not sure why you say that. Our feelings have always been that increased regulation and increased oversight related to all of the stakeholders had the potential to avoid this situation.

M^{me} France Gélinas: Are you surprised, then, that there was no increased oversight recommended for GPOs?

Mr. Kent Nicholson: To be quite frank, I'm not sure that I thought about it before arriving today. That's my honest answer. My honest reaction is the same: I don't have any opposition that we would come under some form of oversight.

Mr. Michael Blanchard: The regulatory oversight for the clinical component of what we do is covered under the hospital. A lot of our decisions and clinical reviews come from our hospital members' various committees.

Certainly, having this additional oversight that Dr. Thiessen has recommended—the specifications may have been standardized for this type of activity. There's no guarantee, but it may have assisted in mitigating this risk.

M^{me} France Gélinas: The idea of concentration-specific medication is such basic knowledge for any professional who works with IV drugs. Whether it's a pharmacy assistant or a nursing assistant, they all know the difference between a drug that is concentration-specific rather than amount-specific. Yet you had a committee in place, Medbuy reviewed, Marchese showed you the label of what they were going to do, it went to the hospital and, all throughout, nobody caught it.

If it had only happened in London, you'd say, "Human error; they did not catch it," but it happened in more. It happened in three. The fourth one finally caught it. That leads one to believe that it is a systemic problem, yet Dr. Thiessen does not talk about the failure in communication. When you talk about what you are doing to improve so that it never happens again—and I believe you when you state on the record that you don't want it to happen again—none of you address that.

I don't know who to address my question to, so I'll go to you.

Mr. Michael Blanchard: Your question is, Dr. Thiessen did not address the failure in communication, or the gap in communication?

M^{me} France Gélinas: And neither did you today when you came and told us about what you have done so that it never happens again.

Mr. Michael Blanchard: I believe we may have mentioned that—or Kent, here, did address that. But we certainly have given serious thought to the whole process and how we could prevent it. Certainly, we acknowledge that there were some assumptions in our methodology that we're certainly taking steps to—the knowledge that we had was based on certain assumptions, and that was a gap in our communications.

Mr. Kent Nicholson: I'll make one comment with respect to—again, in reading an opening statement, sometimes it's difficult to add context for what we have here. But the concept of risk rating and the concept of not only risk rating the overall initiative but risk rating down to a product level, I think, have a real and impactful impact in a situation such as this.

We took 117 products out to market. We did assess risks. From an overall initiative perspective, we assessed risks—things like stability, vendors' ability to supply, and those types of things. We wrote a specification that way.

Had we risk-rated the individual products, I think we would have started to see some groupings. We very likely would have placed at the very top of the list the chemo products in question as being the highest risk, both in terms of handling but also in terms of sensitivity

to dosing. As soon as you identify something as high-risk and do something as basic or fundamental as put it in your RFP in that way, it starts to turn your mind to a different way of taking things to market. That's what we were trying to get to.

If we had identified these four products—two gram and four gram of gemcitabine and cyclophosphamide—as high-risk, and maybe the highest-risk products, we would combine that with the fact that the overall spend on these products was less than \$10,000 on a contract worth \$2.6 million. It may have started to take us in a number of different directions. One is, we could have more clearly articulated the specifications. We could have told the compounder how to compound the product. We could have taken these four products out of this RFP altogether and tendered them very separately. There are a number of things.

Our response to the recommendation was, "We are going to risk-rate every product in every initiative that we take to market." Inherent in that—we take some very large initiatives to market; 117 products would be not a large initiative by our standard. We have initiatives that have hundreds or thousands of line items. Going through a process of risk-rating every one of those products to identify and start to stratify, "What are the highest-risk products within this initiative?", just intuitively and naturally takes your mind to a different way of handling those products. How you do that in each instance is unique to that initiative, but what has unlocked it for us is this concept of risk rating at a product level.

M^{me} France Gélinas: If I come—sorry.

Mr. Michael Blanchard: I was just going to add to your question. We have, in our remediation plan, addressed—Marchese has undertaken to ensure that the communication—to review, with each hospital, the label and the procedure and the formula for preparing the product, and obtaining a sign-off. That's something that we've introduced in the current contract and that we plan in future contracts. This will address that communication gap and ensure that the clinical end user is aware of exactly what they're receiving, and the label. We stated that in our opening.

M^{me} France Gélinas: Okay. Coming back to my opening comments, what would happen if we were to bring you back under a hospital corporation umbrella?

Mr. Kent Nicholson: I'm not sure exactly what—under a hospital? What does that model look like in your mind? Is that part of the provincial government? Is it connected to one hospital?

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M^{me} France Gélinas: You are connected to one hospital corporation.

Mr. Kent Nicholson: Again, if the mandate of that organization is to standardize and group buy and aggregate, I'm not sure how they operate any differently than we do today. They sound like the same thing. It's just that you're resident or connected or tied to one hospital as opposed to the way that we are structured, that all hospi-

tals are equal members and equal voices around our table.

M^{me} France Gélinas: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. We'll go to the government side: Ms. Jaczek?

Ms. Helena Jaczek: Thank you. I'd like to go into a little bit more of your structure. You said that Medbuy has 25 members. There are other GPOs out there. How does a hospital decide if they wish to be involved in group purchasing? How do they decide which GPO to become a member of? What do you offer? Is this a competitive environment?

Mr. Kent Nicholson: Ourselves and our main competitor operate both as not-for-profit organizations. I see Medbuy as a service organization, and our interest is to serve our members well.

How an individual member decides whether they'd like to be a member of Medbuy or a member of HealthPRO is very personal for them. They—

Ms. Helena Jaczek: Well, "personal" usually relates to some sort of business advantage.

Mr. Kent Nicholson: Well, again, the challenge of comparing and contrasting two GPOs—you could request from ourselves and HealthPRO a basket of goods and compare the price of that basket of goods. How big you want to make that basket—we carry more than 100,000 SKUs under contract. The comparison between ourselves and HealthPRO is not a straightforward exercise in terms of what the cost of that basket is, but that would be a consideration. People would do a value assessment.

I think our membership would say that one of the uniquenesses of Medbuy is, we are a little more intimate in our membership. The fact that we've got 25 members—that is a significantly fewer number than our competitor. By virtue of that, I think our membership feels more inclusive and more engaged. Every one of our committees is represented by every one of our membership. That is not the case with our competitor.

Again, the intention of today is for me not to get into a pluses and minuses of—but certainly those are some of the considerations that people might go through in evaluating a GPO.

Ms. Helena Jaczek: Okay. We'll come back to engagement of the membership in a minute.

Just reading from the second page of your presentation today, you say, "Medbuy operates like a not-for-profit in that we do not retain earnings. Any revenue that we generate is distributed to our member hospitals in proportion to their spend under Medbuy contracts."

What revenue do you generate?

Mr. Kent Nicholson: It's generally rebate revenue. Many of our contracts have a rebate structure connected to them, usually based in meeting certain volume thresholds. If our members meet certain volume thresholds, there are additional rebates that are secured on their behalf. All of those rebate dollars come to Medbuy. We take that pool of money, we offset our operating expenses and we distribute 100% of the remainder.

Ms. Helena Jaczek: Explain to me a little bit more about rebates. What are these rebates?

Mr. Kent Nicholson: The total value that we secure from vendors, and again, it's very optional for—a vendor can propose to a proposal any way they want, but it is not unusual for a vendor to—when we aggregate volume, we do better for our membership on the off-invoice price than they can do themselves. Immediately, off the invoice, they get a more attractive price. Then, very often, vendors will put in place some form of rebate structure that incents compliance to the contract and volume aggregation. So if you meet certain volume thresholds, then a rebate kicks in and a rebate applies to all the volume that all of our membership has purchased against that contract.

Ms. Helena Jaczek: So if you purchase a much larger amount of a product, they will say, "We will give you a rebate"? Is it as simple as that?

Mr. Kent Nicholson: What they're targeting is commitment and compliance to the agreement, so if we aggregate all of our volume our members spend and it's \$10 million or it's \$20 million, conceivably they will create—and this is their structure, not ours.

Ms. Helena Jaczek: This is what they put in the response to the RFP.

Mr. Kent Nicholson: This is what they put in their proposal. So they'll give you an invoice price and they may say, "If you hit a threshold of \$15 million, which represents 75% of your spend, we will give you a rebate that equals this. If you go to 80%, it equals this. If you go to 90%, it equals this." Clearly, we're not encouraging members to spend more than 100% of their requirement. That's generally the nature of a rebate structure. It ensures that the vendor gets the volume, and in return for the volume, it gives us further recognition on the price.

Ms. Helena Jaczek: I seem to recall when you came before you referred to value added, that this was a component. Can you explain to us again what that was all about, that some companies offered some financial incentive? I don't remember the rebate issue. It was more some additional funding that was an incentive to choose them.

Mr. Kent Nicholson: I would not consider a rebate related to value-added discussions at all. It's purely part of the financial consideration, and we calculate it in the way that we evaluate the attractiveness of their financial proposal.

Ms. Helena Jaczek: When you're scoring the vendor's applications or proposals, is there a category that refers to value added?

Mr. Kent Nicholson: There was at one point. There is no longer, and that's probably been the practice for two or three years. We do not have a separate category of value add. Within value add, that could be anything from extended warranties to in-service training to attendance at training events, so there's a variety of value-added incentives that used to be part of our structure. What we've now done is, if we can't quantify it financially, if you can't actually translate it into dollars and cents, then

we don't consider it. If we can translate it into dollars and cents, then we include it in the financial evaluation.

Ms. Helena Jacek: Thank you. Now, in terms of what happened, you explained to us the previous way that Medbuy was operating. You stated, "This included requiring the activities to be carried out under the supervision of a licensed pharmacist and referencing the need that the third party compounder adhered to the USP 797 standard, which is considered the pharmacy gold standard for carrying out these activities." So what went wrong?

Mr. Kent Nicholson: Well, again, in my opening remarks and at the end of my opening remarks, in a heartfelt way—and I don't like to simplify things or trivialize things. There were assumptions that all of the stakeholders made. We made assumptions; Marchese made assumptions; the hospitals made assumptions. Unfortunately, those assumptions, in some instances, were incorrect.

Ms. Helena Jacek: Okay, so you talked about engagement of your membership. Who was on the committee that reviewed Marchese's proposal and the others that submitted proposals? Who was physically at the table with the proposals in front of them?

Mr. Kent Nicholson: I think I'll turn it over to you, Ann, maybe to talk about how the RFP is scored and that process.

Ms. Ann Kelterborn: For the RFP scoring, we have a representative from each member, as Kent was saying, and those—

Ms. Helena Jacek: Each of the 25—

Ms. Ann Kelterborn: Each of the 25 belong to our pharmacy committee. In general, their expertise is senior-level pharmacy. They're generally the directors or managers of pharmacy who are, in a sense, still connected to their internal experts. When we develop the criteria, we develop that criteria with them up front at the table and review that. We have biannual meetings with them as well as monthly conference calls.

In the case of when the proposals are received, those are sent out along with the criteria, and the members score those independently, so we eliminate that bias or that group. We're not all in a room together scoring something at the same time. Everybody is independently scoring it. Those are collected, collated and the final result is established.

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At the same time, from the financial part of it—because the members score the non-financial, along with ourselves, components of that. Financial is done corporately, as it is with all of our initiatives, and that's done separately. So you are doing your non-financial and your financial. Those come together, and they roll up to produce a total score.

Ms. Helena Jacek: Did any of those 25 members make a note of the issue related to concentration and specificity? Did they recall anything about the previous contract with Baxter? Was there any—

Ms. Ann Kelterborn: Not to my recollection. When our scoring is done, it's done according to a template that is established with criteria. There are scores of zero to three. Which place you land in that scoring grid depends on your answer, and your answers that we are looking for, from a zero to a three—they could be binary answers or judgment-call answers, and that's how it's put forward, and the members will score according to what the responses were in the RFP.

Ms. Helena Jacek: And then these—

Interjection.

Ms. Helena Jacek: Sorry. Did you want to say something?

Mr. Ron Swartz: Yes, I think I'll just supplement a bit. It's that all these criteria—I mean, we generated the first draft of the criteria in terms of looking at the literatures and standards that are available of the day. These criteria then go to the committee, and they're thoroughly discussed at the committee and approved by the committee. I think 10 members of our committee contain regional cancer centres inside their facilities, so whether in a committee or in their staff, there is very large amount of oncology expertise.

Ms. Helena Jacek: So in reviewing the minutes of the pharmacy committee—I presume you have minutes and so on—there were no questions raised related to labelling concentration, how the product was going to be produced?

Mr. Ron Swartz: No. Our view still is that all the products listed there were concentration-specific. We asked for a specific strength of a drug, amount of a drug and a specific volume of fluid in there. It's the same item list that we'd used before. Many members have been buying some of these products for years without incident.

Truly the standards, at the time, did not address this in any real away in terms of labelling. I guess they, like us, didn't envision this type of error happening, and so they had not addressed it.

Ms. Helena Jacek: And the USP 797 standard would not have specified how the admixture was to be produced?

Mr. Ron Swartz: No. It's a technical standard that really looks at the room and airflow in the room and changes like that. It looks at staff training, staff testing, how often they change their gloves, what sort of testing should happen in terms of, if I were doing microbiological testing of the hood, am I going to do end product testing or not?

Ms. Helena Jacek: But it doesn't actually talk about how you mix the stuff?

Mr. Ron Swartz: No. Well, it talks to it in terms of the process of putting in sterile, in terms of keeping a clear airflow in—because they use laminar flow hoods. These are devices that create sterile air—not quite sterile air, but very close to sterile air. It blows out parallel to you, so they talk about ways of positioning products in there so as you're not contaminating from one product to another in different production and things like that.

Ms. Helena Jacek: So the—

Interjection.

Ms. Helena Jaczek: Yes.

Mr. Michael Blanchard: The drug monograph itself outlines specifically how to prepare the product, and the pharmacist would have relied on that information.

Ms. Helena Jaczek: So the expectation, presumably, in the case of awarding the contract to Marchese, was that the compound would be mixed and the end result would be the four grams per—

Mr. Michael Blanchard: Yes. That the overflow would have been taken into account, as per the instructions.

Ms. Helena Jaczek: So that as you've reviewed all your notes, that was, presumably, the assumption of the people of that time.

As you move forward, explain to me again—and you have, to a certain extent—exactly how this will look in the future, should you choose to continue to use a compounding process or purchase these types of products.

Mr. Kent Nicholson: I'll start and maybe the team can jump in. But, as I've described, if I were to restart this process, I would take a look at the basket and I would risk-rate every product.

Inherent in that, I would start to stratify: What are the highest-risk products in this RFP? In all likelihood, for those products that are highest-risk, we would have a more detailed specification, at minimum, that we would write.

We did not feel it was our role to tell the compounder how to compound product, but our experience recently and what we've gone through would indicate, for those high-risk products, that we probably would take the step to say, "This is what you do: You start with an empty bag. You do this, you do this, you do this, you do this."

As I said, we may include that particular activity within this larger RFP or we may break it separately and award it separately, if we felt that that was in the best interests of patients and our membership.

Ms. Helena Jaczek: I guess I'm a little puzzled. You've been around since 1989. You have all this expertise from the membership. That this concept of risk, in terms of compounding being really a different thing than just supplying tablets of a certain type, wouldn't have come to the fore—just help me with that.

Mr. Kent Nicholson: Well, we've tried to describe that we have always considered risk when we undertake our work. If I jump to the med-surgery portfolio, we will identify initiatives that have high clinical sensitivity, and those are initiatives that we engage fully with our expert committee. We also assign an ad hoc committee, experts beyond even our committee. We have an operating room committee, and no one sitting on the operating room committee is an expert in everything. So if it's a highly clinically sensitive product, we will develop a specific ad hoc that supports that particular initiative.

In our legacy, in our history, I indicated that we've had a flawless record. We've never had an incident such as this. We do attribute it to bringing subject matter

experts around the table to help us in the work that we do.

In this particular instance, we relate it to compounding service. We certainly focused on risk, and I think Ron has touched on some of the risks that we thought were inherent. We never thought the risk was that somebody would compound to the incorrect concentration, or overlook or overfill or disregard that, or that a package would leave a plant with a very clear label on it and the product not match exactly the expression that was on the label.

We did spend a lot of time thinking about aspects of sterility and stability. We did run this initiative with the same diligence that we've always employed. Unfortunately, we ran into a situation that we've never had occur.

Certainly, most of the products that we acquire, 99.5% of the products we acquire, are licensed by Health Canada for sale in the business that we do. As it relates to the med-surgery portfolio, we are not buying a service or product that is not approved for sale by Health Canada, so that gives you a level of comfort that only those that carry a licence can put their hand up and operate in this area.

Ms. Helena Jaczek: Thank you. Just again, explain to me the role of the subcommittee. You mentioned you're going to put in place a new pharmacy subcommittee. What's the purpose and who is on that?

Mr. Michael Blanchard: First of all, this is standard practice, that whenever an initiative is reviewed, prior to going out to renew a contract for any particular product or group of products, the pharmacy committee members strike a working group to review the process, to identify opportunities to improve the exercise.

In this case, the committee is focusing on Dr. Thiessen's report. He identified four areas that we're going to be specifically looking at. We've engaged a facilitator to help us through this exercise. We've also engaged an independent expert consultant from the Institute for Safe Medication Practices. The scope they're going to be looking at is essentially four areas: the specifications, the transition, the clinical sign-off—the end-user validation—and the fourth was—I can't remember.

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Ms. Ann Kelterborn: The risk rating.

Mr. Michael Blanchard: The risk rating, yes, which we've already started.

Ms. Helena Jaczek: So before any future RFP goes out—

Mr. Michael Blanchard: Yes, the decision to renew or not renew this contract or to continue participating will be pending the recommendation from the subgroup. The subgroup is made up of expert members from various hospitals. I believe there are eight hospitals. All four affected hospitals will be participating, and some non-affected hospitals. One of the hospitals, I think, never used the service, but they will. So we have a broad spectrum of participants.

Ms. Helena Jaczek: In case you do go out again, they put that together, the RFP goes out, and then you will return to the same model of evaluation, I presume, with your entire pharmacy committee, with each hospital member—

Mr. Michael Blanchard: This committee will put forth recommendations to the main committee, report back, and then a decision will be made. If they do move forward, then I'm sure the recommendations to implement some additional safeguards and checkpoints and introduce more checks and balances in the system have force functions to ensure that certain quality control checkpoints are documented.

Ms. Helena Jaczek: Thank you. I'll just reserve—

The Chair (Mr. Ernie Hardeman): Thank you.

The official opposition: Ms. McKenna.

Mrs. Jane McKenna: The first question I have is, isn't it the responsibility of the broker to take the risk value out?

Mr. Kent Nicholson: Could you help me understand that?

Mrs. Jane McKenna: Just going back a few minutes ago, you were speaking about how there was a lot of assuming and assumption. But there shouldn't be any interpretation when you have a contract that you've put together. It should be very specific what you're expecting from the person who assigned that contract. I always want to figure out, where does the buck fall? I understand that everybody has, maybe, some ownership in it. But if I get a contract from somebody and it's specific in there what my expectations are in that contract, there should be no interpretation or any assumption at all. To me, as a broker, that's your responsibility. I could be wrong. That's why I'm asking you that. Is it not your responsibility as a broker to have clear and concise information in there so there's no interpretation anywhere; nobody's assuming anything?

Mr. Kent Nicholson: I would agree. We accept that responsibility. Again, the way that we exercise that responsibility and have always exercised that responsibility is to engage our member hospitals, who are experts, front-line patient caregivers who use the products. This particular initiative was no different than that. We had the pharmacy directors around the table reviewing the specification, reviewing the clinical scoring, reviewing the proposals that were submitted.

Again, I think the step that we've highlighted two or three times that may make a difference going forward will be to risk-rate individual products and identify products within large RFPs that are higher-risk, and inherently, they will get a further level of detail, specification, discussion.

This unfortunate incident came down to someone asking a question. Somebody in Peterborough said, "Is this an exact concentration?" That's all it took. We could have asked that question; Marchese could have asked that question; the hospital could have asked that question; anybody could have asked that question, all the way along.

Trying to utilize this exercise of risk-rating products to identify the highest-risk products, to eliminate, going forward, any need for assumptions or an interpretation, is exactly what we're recommending that we do.

Mrs. Jane McKenna: I'm just reading through what you have here. Sorry, the page isn't marked. You're going to now be changing your contract with these specific things in here. Just going through this whole process, when Baxter was in here, when they started back—and I don't remember the actual time, but their relationship was a relationship that was built with the pharmacists, back and forth, open communication. So whenever there was a question, there was open communication. They didn't go through anybody else to get those answers.

You having to write a contract on something that is very tatorial, that's very hands on from another company, would be very hard to do, as far as I'm concerned. So when you were doing this contract, you can clearly see in it, right—and I'm not saying it wasn't done intentionally or any of those things, so please, that's not what I'm trying to say. What I'm trying to say, though, is that there weren't specifics in the contract clearly or we wouldn't have the problems that we're having. Why is that? I'm just wondering, if you had the actual model—and I realize that there are differences—why is it that one company was so clear on what that process was and yet this company was not?

Mr. Kent Nicholson: I think there is probably something to the fact that they had a legacy relationship. Baxter's relationship for this particular service predates our involvement in any contracting. The first time we were here to the committee, we indicated the very first contract we ever put in place was in 2008. Prior to 2008, many hospitals already had a relationship with Baxter. So our membership came to us, saying, "Could you aggregate this? Could you standardize this? We're all using Baxter. Could you go out on our behalf for a contract?", which we agreed to do on the condition that they're going to be participative in the construction of that specification, the evaluation of the proposals, and we did that in 2008.

At that point in time, the only proponent was Baxter and so that specification carried forward from that point forward. It was a list of products. Every one of those products was intended to be an exact concentration, and we utilized that list when we went to market a second time. Our intention was to continue a relationship with Baxter, but the process of declaring that this is something we wanted to tender, we believed it was sole-source. We had an objection to that. We reviewed the objector, their capabilities. We thought it was a valid objection and we put it out to market and received three bids. So I think there was, based on a legacy relationship, more intimacy that Baxter had with the hospitals.

One of our recommendations very specific to the current Marchese contract is for this service in particular, because it is—you're not manufacturing a product, but you are compounding. You're not buying a pacemaker

that's assembled. You are taking components and you're putting it together and you're providing it to the hospital for use. So our recommendation with Marchese has been, "You must meet with every hospital member, and you must describe your process for formulation. You must describe the label you're going to put on this product." There will be a sign-off between the hospital and Marchese confirming that both parties understand the requirements and they match the way the product is used in that particular hospital.

Mrs. Jane McKenna: Okay. So my next question is—Ms. Gélinas asked if you would be open to oversight. I didn't really get your full answer of yes, 100% you would be. I'm just saying, for me, it would just alleviate if someone else was overseeing exactly what you were doing, and I would welcome that. I'm just saying myself, just because of the situation that we've all been in here. So did you say that you 100% wanted oversight?

Mr. Kent Nicholson: It wasn't clear to me who that is and how that works but—

Mrs. Jane McKenna: Well, it would be ministry oversight. It would be the ministry ultimately in the end; right?

Mr. Kent Nicholson: But again, we cross provincial boundaries. If there was some form of oversight that was struck to say, "Let's review periodically the work of GPO, how they do that work, how they execute," we would welcome that. I can think of nothing bad that can come out of that and only good could come out of it, to have somebody independently take a look at the work that you're doing with a fresh set of eyes and a new perspective. Sometimes we're too close to the work that we do and so I have no issue. I don't know how to do it, but I would have no issue with that form of oversight.

Mrs. Jane McKenna: Okay.

The Chair (Mr. Ernie Hardeman): Mr. Yurek?

Mr. Jeff Yurek: Thanks for coming out again. Does Medbuy have a quality assurance program in place?
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Mr. Kent Nicholson: Certainly, we are asked by our membership to attest that the work that we do is compliant. We do review the execution of our work, that it follows steps that are prescribed.

Do we have a separate quality committee? No, we don't, but we are asked by our membership on an annual basis to attest that we are compliant.

Mr. Jeff Yurek: So you have no—

Mr. Michael Blanchard: Well, the work of our committees in terms of our business processes, as Kent mentioned—there's that aspect of quality: Do we comply with the guidelines and the procurement directives and so on? There's that aspect.

I assume you're looking at whether we have a quality program in place to ensure that the products that are put under contract meet those quality standards.

Mr. Jeff Yurek: Just in general, I would have assumed that a \$627-million corporation would have quality in place. I'm quite shocked—I was expecting you'd say, "Yes, we do."

Obviously, I hope you've learned from this, that without a quality system in place in your corporation, you have communication gaps, and you have assumptions that occur, that lead to people not getting the right chemo drug at the end of the day.

Mr. Michael Blanchard: Well, that's part of our exercise where we hired that external process expert.

Mr. Jeff Yurek: Further to that, what has come up through committee—I asked each of the hospitals when they did attend—the front-line health care workers: Is there a complaints process that the front-line health care workers can send to Medbuy and say, "I have a problem with X product"?

Mr. Michael Blanchard: Yes, they do.

Mr. Jeff Yurek: Each one said no.

Mr. Michael Blanchard: Ann, maybe you can address that. We do have a web-based reporting system.

Mr. Jeff Yurek: And front-line health care workers can access that, or do they have to go through their manager or somebody's manager?

Mr. Michael Blanchard: Yes, the buyer and—well, Ann, I'll let you—

Ms. Ann Kelterborn: They would access that through our e-catalogue. Those who do have access—

Mr. Jeff Yurek: Front-line health care workers don't all have access to that.

Ms. Ann Kelterborn: They don't, but they can always have access to it. It's just an application process to us through their committee representatives.

I'm saying that in a number of hospitals, there are a number of folks, from pharmacists to technicians to buyers, who may touch or be involved in products, who can actually go online or contact their representatives from the committee and have those people post online or contact us.

Mr. Michael Blanchard: There is a structured process within the hospital and within Medbuy. If a front-line nurse, for example, has a product problem, within most hospitals there's a reporting system and mechanism. They would report back to the pharmacy buyer, who would then report to us, and that is structured.

Mr. Jeff Yurek: Okay, but that's broken, because the front-line health care workers who testified at this committee do not know of that process. I'd recommend to you to write that down too, in your reviews. I would assume that, going forward, you would head towards a quality assurance program but in that fact, that you would be open to expanding the ability of those complaints to get to Medbuy.

Mr. Michael Blanchard: That's surprising, because we usually review those complaints, and they're documented and reported to the committee on a monthly basis for discussion.

Mr. Jeff Yurek: But if they don't reach you, you don't get them.

Mr. Michael Blanchard: Well, it will be interesting to find out which front-line hospital—

Mr. Jeff Yurek: All of them.

Mr. Michael Blanchard: All of them?

Mr. Jeff Yurek: All of them.

Mr. Michael Blanchard: That's—

Interjection: I think the question—

Mr. Jeff Yurek: I hope that you're just not going to be defensive.

Mr. Michael Blanchard: No, but it's—

Mr. Jeff Yurek: We're trying to make sure that this does not occur again, right?

Mr. Michael Blanchard: I understand what you're saying.

Mr. Jeff Yurek: Okay.

Mr. Michael Blanchard: But I'm just plainly surprised, because I've only been at Medbuy for a few months, and the documentation that I've reviewed, and so on, would indicate otherwise.

Mr. Jeff Yurek: Going to the RFP procedure, this was the first time to send out a request for proposal for admixed products, correct?

Ms. Ann Kelterborn: Yes.

Mr. Jeff Yurek: How did you create the RFP? What resources did you use then to develop that RFP?

Mr. Ron Swartz: We looked at the standards of the day that were available. I had actually attended a US conference where one of the sessions was on the outsourcing of sterile compounding, so I got information from there. There is a set of guidelines or a process for outsourcing from the American Society of Health-System Pharmacists, so we had that. We looked at USP 797, really specifically around the processes. Specifically, I was looking at that around the training and testing of staff and what's going on. I looked at GMP, Canadian Good Manufacturing Processes, for the same thing, to try to draw all these standards in. It's well recognized, and this has been discussed very early on in the committee, that there was no oversight for this group; therefore, we have to be very sure about the process that we're doing to do this.

As well, as you may know, there have been many problems in the US with unsterile products getting into the marketplace from these compounding agencies—a number of deaths reported down there. If you see the FDA warning list now, they're regularly doing recalls on products from this. We're very aware of the sterility issues. That's really what the focus became, because that was the focus of pharmacists at that time, both in the US and in Canada, because these are the issues that have been identified. So we used those.

Then the rest of it just came from the committee in terms of, "Do you want pharmacist oversight?" "Yes." We don't have to license pharmacist oversight. So they would make those kinds of recommendations to that. So we spent virtually a full afternoon at a committee meeting with the committee going line by line over all these criteria and reviewing it.

Mr. Jeff Yurek: Did anybody on the committee have experience with contract preparation and RFPs in general, or was it just the health care professionals?

Mr. Ron Swartz: They're all just health care professionals, but they're all directors of pharmacies, so many have done RFPs. If they've been part of the pharmacy

committee for a time, and many have, then they've got the experience of being involved in the development of other RFPs.

Mr. Jeff Yurek: How long did it take to develop the RFP?

Mr. Ron Swartz: Well, we started talking about it in 2010 at some point, so really we started working on that from there. Actually, I think the conference was in 2009, mid-year. I went to that conference. We had been thinking about it for a while, and there was considerable time spent in looking at the literature and drafting the criteria.

Mr. Jeff Yurek: Do you have—

Mr. Michael Blanchard: I was just going to say that in reviewing the minutes and so on, they spent well over a year, almost on a monthly basis, in discussions around developing the RFP and the criteria.

Mr. Jeff Yurek: Did it ever come across to perhaps use Baxter in your creation of the RFP since they were already providing this service?

Mr. Ron Swartz: No. We had regular business meetings with Baxter. Many of us had site visits to Baxter, so we were somewhat familiar with their process. We had seen it. But they were going to be one of the competitors in this RFP, so we weren't necessarily asking them to write the RFP to give them the most favourable outcome. We were looking at the standards and criteria of the day and trying to develop those into measurable criteria from which we could be comfortable with the outcome.

Mr. Jeff Yurek: Was there ever a thought to contacting the CCAC, since they've been working on RFPs for various items for years on end and keep re-evaluating their RFP process in building upon it?

Mr. Ron Swartz: No, there had been members who actually had CCAC contracts or hospitals outside our membership who had CCAC contracts, so that expertise was there. The CCAC focus is very different. It's home care. It's patient-specific. It's for the individual prescription through a licensed pharmacy. It's quite a different process from the batch compounding process. It's a sterile process in terms of putting the drug in the bag—yes, it's exactly the same—but in the general process there would be significant differences.

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Mr. Jeff Yurek: Do you have a committee that is reviewing your RFP program and continually monitoring and updating the RFP processes, contracts?

Mr. Ron Swartz: We regularly would look at lessons learned from our past documents. In terms of our major RFP cycle which are going out next year, we already had developed our strategy committee and we have a task force or a project force on general RFP criteria. So they have looked at this; it's gone out to the committee. We gather the comments from the committee after the last award and bring that into this process. So we have what we identify as a "lessons learned" document, which we use to correct faults going forward.

Mr. Jeff Yurek: Now, with regard to the changeover from Baxter to Marchese, we also learned in committee that it was rocky. Have you looked at your changeover procedures for when you do switch a supplier, have you reviewed with staff what went wrong, and are you implementing changes in that?

Mr. Ron Swartz: I can start this and you can go from there.

Ms. Ann Kelterborn: Sure.

Mr. Ron Swartz: Yes. I mean, we would argue that it was rushed, and whether it was rocky—I think that the handover process or the change in management process wasn't much different than it would have been for many RFPs. I think the fly in the ointment, as it were, was the unwillingness of certain suppliers to sell direct to Marchese, and it was this process—which we weren't aware of until we made the award either. I think that process contributed more to issues in transition than really the product-to-product transition, because in the end there was a sterile drug in a bag, and that's what they'd been getting and that's what they would be getting.

Mr. Jeff Yurek: Did you want to add something?

Ms. Ann Kelterborn: I just wanted to mention the subcommittee that has now been struck. According to Dr. Thiessen's recommendations, that will be one of the areas that they will be looking at and reviewing on a go-forward basis for what would need to be in place if we do this initiative in the future.

Mr. Jeff Yurek: Just a couple more questions for your comment, because this also came up during committee. I was reviewing my notes, and during Marchese's deputation they stated that Medbuy and Marchese did have a conversation about overfill during the contract negotiations. Can you comment on that?

Mr. Ron Swartz: We did. The conversation was with respect to antibiotic bags. So if they came to us and said, for instance, "With a Cefazolin one-gram bag, where we know for certain it's a single-use, is the overfill an issue?", our answer was, "No, it's not chemically because you're administering the whole bag." That then got applied to a broader range of products as being single-use bags, and that was never in the conversation.

Mr. Jeff Yurek: It also was brought up that—it was noted that their labelling was superior. Nobody said it was unclear, yet some of the hospitals did not like the labelling. Any comments on that?

Mr. Ron Swartz: Labelling is always—there's always a judgment to this. They were superior in two ways; there were really two sets of superiority we saw from Marchese. One was just customer service, which we felt was superior to what Baxter was offering. The second, with respect to the labels—the biggest component was bar-coding. There's a very large movement in hospitals to bar-coding to the bedside. It's a well-documented, well-recognized patient safety measure. A number of hospitals are bar-coding products now, so the availability of a bar-coded product was a significant advantage to many of our members.

Mr. Jeff Yurek: I'll put my time to the next—

The Chair (Mr. Ernie Hardeman): Okay. Third party: Ms. Gélinas.

M^{me} France Gélinas: How long do I have left?

The Chair (Mr. Ernie Hardeman): Twenty minutes.

M^{me} France Gélinas: I'll start with this. You have put into place a series of very good quality improvement steps that you read in your opening statement: the risk assessment of individual products; the sign-off back to the end users; the clarity of the label with single dose; the range of volume; that kind of stuff. To me, those are all good quality improvement steps.

If it wasn't for this committee, how would we have found out and who knows that you're doing this?

Mr. Michael Blanchard: Our members are. Certainly the committee members, yes, this whole—what we refer to as a remediation plan has certainly been developed with input, and we've got our pharmacist members on the committee. All the hospitals that are utilizing this product and some that continue to use the services from Marchese have been involved and are kept up to date.

M^{me} France Gélinas: Do you know if any of the other GPOs are also learning from what happened?

Mr. Kent Nicholson: I don't know first-hand. I would expect that everybody in health care procurement has followed this and has followed the incident. It's not only GPOs, but there are regional shared services organizations that also act on behalf of hospitals to acquire product. So I believe everyone is well aware of the situation and is well aware of Dr. Thiessen's report. I can't comment as to what actions they are taking.

M^{me} France Gélinas: Okay. Let's say you would stop using one of the new quality steps that you've put in place. How would we find out and who would know?

Mr. Michael Blanchard: If we stopped?

M^{me} France Gélinas: Yes.

Mr. Michael Blanchard: I have no intention of stopping any of this.

M^{me} France Gélinas: Okay.

Mr. Michael Blanchard: But to make sure, as our pharmacist friend here, Mr. Yurek, has stated, we certainly have started some quality assurance. We've introduced quality assurance components in our processes, and we will continue to enhance that whole—and turn it into a formal program with reporting. My intention is to develop a set of quality control metrics.

Mr. Kent Nicholson: Just further, this is not the first time that we have talked about our response to Dr. Thiessen's report. We have communicated these action steps just as they are to our complete hospital membership—to the CEOs, to the CFOs and to all of our board members: "Here is our response; here is our action plan as it relates to Dr. Thiessen's report." So we've been very visible and very transparent, in the spirit of, we're fine to be held to account. I would fully expect that some of those or all of those CEOs—certainly, my board, who are representative of hospital executives as well—are going to consistently test for our follow-through on the work that we've started.

M^{me} France G  linas: So, talking of reporting, I take it you do yearly financial statements. Do you have your financial statements audited?

Mr. Kent Nicholson: Yes, we do.

M^{me} France G  linas: And who has access to those audited financial statements?

Mr. Kent Nicholson: The board.

M^{me} France G  linas: Okay. Are they available? If anybody was to ask you for a copy, are they available, or solely to your membership and your board?

Mr. Kent Nicholson: Certainly making them available to the standing committee, I have no issue with, but making them broadly, publicly available, I just need to double-check in terms of whether there is any competitor or confidential information that is contained in there.

M^{me} France G  linas: But it hasn't been your practice to make those broadly available? You report to your members and to your board, then?

Mr. Kent Nicholson: Correct.

M^{me} France G  linas: That's where it ends? The people that work for you: Would they be on the sunshine list if they make more than \$100,000? Are you covered by the sunshine list?

Mr. Kent Nicholson: No.

M^{me} France G  linas: No? Do you do it voluntarily just to show transparency?

Mr. Kent Nicholson: We don't.

M^{me} France G  linas: No? And do you have employees, within the 60 that you talked about, that make over \$100,000?

Mr. Kent Nicholson: Yes, we do.

M^{me} France G  linas: And out of 60, how many would you put to that?

Mr. Kent Nicholson: Perhaps five.

M^{me} France G  linas: Okay. Do you know if any other group purchasing organizations do admixtures purchasing?

Mr. Michael Blanchard: Come again, please?

M^{me} France G  linas: We know that Medbuy did put out a request for admixtures. Do you know if any other GPO has done the same?

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Mr. Michael Blanchard: I can't speak for all of them. I'm not aware of any. It might be—

Mr. Kent Nicholson: I think it in part speaks to what your definition of a GPO is. My suspicion—again, I don't have the absolute facts, but we have some provinces that have provincial shared services organizations, where participation with that shared service organization is mandated. I believe some of those provincial shared services organizations outsource their compounding service.

Mr. Michael Blanchard: It might be a few across the country, but I can't—it's speculating.

M^{me} France G  linas: Okay. That was the first time for you?

Mr. Kent Nicholson: It was 2008; 2008 was the first contract we ever put in place, and again, it was at the request of our membership, because they already were

outsourcing this activity. They were all using Baxter, so they asked us to do this on their behalf, which we did.

M^{me} France G  linas: Okay. How much sharing of best practices exists between GPOs?

Mr. Kent Nicholson: It depends on what you refer to as "best practice." I think that there's some level of competition—we are competitors at some level—but we do come together on issues of commonality. In drug shortage issues, there's a working committee where all of the GPOs and a number of the provincial shared services organizations are represented—so issues that have large-scale impacts on the health care system, where it makes sense for us to be part of a collaborative working group, we do so willingly. Sharing a best practice in terms of how I undertake the contracting process and so on: That would be viewed in some respects as competitive.

Mr. Michael Blanchard: Another example would be bar-coding, where there's been a collaborative effort, developing bar-coding to the patient.

M^{me} France G  linas: Okay. So the industry does not meet to share best practices, or you don't belong to an association together or anything like that?

Mr. Kent Nicholson: I sit on the GS1 CareNET board, and so does my colleague with HealthPRO. Again, GS1 is a standards organization which is attempting to drive unique identifiers for all health care products—not only pharmacy products, but all health care products—to have a unique identifier to be able to track and recognize and recall anything related to the hospital sector in the same way that bar-coding is universally accepted in the grocery industry; it's universally accepted in the retail industry. It has not evolved in health care, which is quite counter. You would think it's more important in health care than in selling a can of peas, but it's the opposite.

Again, making bar-coding an important part of the label criteria was our effort and our committee's effort to move that initiative along for something that makes absolute sense.

M^{me} France G  linas: My colleague will ask a question now, and I'll come back.

Mr. Kent Nicholson: Sure.

Ms. Cindy Forster: Good afternoon. When Dr. Thiessen was here earlier today, he indicated that when you went out with the RFP for 752 products—

Mr. Kent Nicholson: It was 117.

Ms. Cindy Forster: —117 products, Marchese was already dealing with 752 products, and those included the two chemotherapy agents in question. Then when I asked to clarify that after the fact, he wasn't sure whether or not, in fact, Marchese was already dealing with those products before your RFP within their facility or whether they were doing it, perhaps, in the community, based in their local pharmacies. Can you shed some light on that? They said that it was a question that perhaps Medbuy would better answer.

Mr. Ron Swartz: I don't know for sure what products on that list they were making. The gemcitabine and cyclophosphamide that are on there seem to be our identifications for those, so they may have just been

added. But certainly, when I saw their facility in Kitchen-er, they did have a chemotherapy preparation area. That was one of the things that we had looked for: “Do you have that?” Yes, they do. “Do you have staff trained to get all the different stuff needed to go in there?” Yes, they have. All the requirements were there. They were certainly prepared to make some. I would assume—again, without knowledge—that having the space prepared and functional would say to me that they must have been using it for something.

Mr. Kent Nicholson: It came to us as part of the validation process. When we went out with a single-source validation, we were expecting to renew our contract with Baxter. In their objection, they gave us back a product listing. If it totalled 752, you might know—

Ms. Cindy Forster: Right.

Mr. Kent Nicholson: I was worried about our list. So this is what they represented. “Here is the justification of why we’re absolutely in the compounding business, and we actually have a more extensive list of products that we compound currently than you’re going out for RFP on.”

Ms. Cindy Forster: Well, that’s interesting, because when the pharmacists were actually here from Marchese—there were a number of them—we asked a question of each one of them with respect to their experience around admixtures or compounding of chemotherapy agents, and all of them indicated minimal or no experience in that area. That’s why I asked the question. Do you have any insight into that?

Mr. Michael Blanchard: From what I’ve seen and read, essentially, the question was asked and they objected. Our initial intent was to single-award or sole-award to Baxter and renew the contract with Baxter. They objected and provided us with an extensive list of products that they prepare currently. In that list were oncology items, and, as Ron stated, at our site visit we observed an oncology preparation facility.

Ms. Cindy Forster: Thank you.

M^{me} France Gélinas: There was a breakdown in communication, Dr. Thiessen told us, at every level. The hospital didn’t tell Medbuy; Medbuy didn’t tell Marchese; Marchese sent it back to the hospital; nobody knew that the bag we were dealing with was not concentration-specific and the underdosing arose.

The mere fact that you exist means that there are more handoffs. I take it that you all have a health care background. Every time there is a handoff, there is a risk of error. How do you compose with this, because you have become a middle person in between, that the fact that you exist brings a level of risk to health care that was not there before?

Mr. Kent Nicholson: Maybe I haven’t been effective in terms of trying to describe how our committees work and the degree of engagement and interaction.

We are owned by our members. We are them and they are us. We don’t make decisions without their involvement. Do we create additional handoffs? In that model where we work so collaboratively, I’m not sure we do,

but if we acknowledge that there were handoffs, the alternative to us existing would be that each individual member hospital would have to write their own RFP, would have to take it to market independently and would have to write their own specifications. Very likely, we would have a number of different suppliers, potentially, with a number of different labels and with a number of different scoring criteria.

In that model of 75 individual hospitals contracting for this service independently—I’m not quite sure which of those two models introduces more risk. I might say that 75 independent events as opposed to a single event where we bring together subject-matter experts to build a standard specification and standard criteria is actually a method of reducing risk, but that’s a subject for debate.

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M^{me} France Gélinas: I’m guessing it would be more like 25, because you have 25 members, some of them having many sites.

The legacy relationship between Baxter and the hospitals is basically what assured quality. We’ve just severed that relationship, and yet there was no attention being given to quality. You were about to sever something that assured quality, and you did not replace it by anything else. How could that be?

Mr. Kent Nicholson: We took what we thought were appropriate steps to ensure quality. The fact that we severed a relationship with Baxter—I’m not sure I would categorize it that way.

These hospitals, again, do not have the latitude to just continue a relationship without assessing the potential for other competitors to compete for this business. So, by virtue of the fact that we existed, we didn’t create a requirement to take this out for competitive RFP.

As Ron described, in terms of spending a number of months building the criteria, building the specification, engaging our members, we felt we were doing all the steps that we could contemplate to have a quality outcome.

The Chair (Mr. Ernie Hardeman): Thank you very much. We now go back to the government side: Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. One of the issues that I think we’ve all wrestled with is, Marchese Hospital Solutions assumed that the entire bag was going to be used for one patient. They apparently did have some communication, because there was some idea that they were going to provide an IV connection out of the bag. Did they communicate that proposal at any time to Medbuy, and if so, to whom?

Mr. Ron Swartz: Yes, they did. They asked me whether or not I thought that the members would want IV lines attached to any of their bags. I said they did not, because various hospitals have various practices on that, and the hospitals are going to label it anyway.

To me, it was a straightforward answer to a straightforward question: “Do you want the set attached?” “No, I do not.”

I didn't say or didn't imply in that—in my mind, anyway—that that meant that it was a single-use bag.

Ms. Helena Jaczek: It didn't? I mean, surely if it's an IV connection, it's for one person? You're so concerned about sterility. That would have been an obvious conclusion to their inquiry.

Mr. Ron Swartz: Well, then, all the more reason why we wouldn't want a bag set on there. If we'd said yes, then it's a greater inference than if I'd said no.

Ms. Helena Jaczek: But why wouldn't you say, "Are you assuming that this is to be used for one patient?"

Mr. Ron Swartz: Because the question was, "Do I want a set attached?" and my answer was no.

Mr. Michael Blanchard: It was a question that came from them and that applied to all of the products, just not the—

Ms. Helena Jaczek: But including chemotherapeutic agents. You, of course, were aware yourself that the bag was going to be used for multiple patients.

Mr. Ron Swartz: I'm aware that oncology doses are calculated individually by patient size and protocols, so that a one-size-fits-all product is not going to work in oncology treatment, yes.

Ms. Helena Jaczek: I think your answer is yes, you knew the bag was to be used for multiple patients.

Mr. Ron Swartz: Yes.

Ms. Helena Jaczek: In relation to the fact that when you went to Marchese Hospital Solutions, they were preparing chemotherapeutic agents; they were admixing—you observed this process?

Mr. Ron Swartz: I observed them admixing some products. I don't think they were necessarily chemotherapeutic products. But they did have a space that was functional and certainly appeared to be used—the responses in the RFP with respect to oncology products in terms of special packaging, shipping and handling—they certainly were aware of that, because they answered those quite well.

Ms. Helena Jaczek: Did you ask them if they were supplying admixed chemotherapeutic agents to any facilities?

Mr. Ron Swartz: No.

Ms. Helena Jaczek: When you talk about bar-coding—I can understand the utility of bar-coding when you're relating a specific product to a specific patient. You've got a wonderful way of tracking the product and ensuring that a particular patient has received that product.

In a case where bar-coding is used for a bag to be used for multiple patients—this was considered useful? Can you just explain that to me?

Mr. Ron Swartz: Well, the bar-coding would still transfer into their system, and so it would give you a sense of serialization, so you'd know exactly what bag was used to prepare which products. So if a patient issue arose after, I would know which bag that came from, because that would get transferred in the information onto the patient-specific bar code by the hospital.

Ms. Helena Jaczek: So you would know that a number of patients had received that particular product from that particular bag.

Mr. Ron Swartz: They would be able to know that.

Ms. Helena Jaczek: But it wasn't patient-specific. Okay. I understand.

Overall, I guess through the course of our inquiries—and you've heard from my colleague Ms. Gélinas, I guess we're trying to understand the value that you add to the system other than sort of a cost. You've got bulk, you've got volume, so the manufacturer is going to lower the cost and provide that, and that's a flow-through savings to hospitals. But how much does it cost to run your organization? You talked about, I think, 60 employees. What kind of budget are we talking about?

Mr. Kent Nicholson: It's in the range of about \$7 million annually. In my opening statement, I made reference that we have saved hospitals hundreds of millions of dollars, and that's a real number. Last year alone, we took to market about \$300 million of spend and saved our membership about \$36 million against what they were previously paying, which would have been a contract that we also put in place.

Ms. Helena Jaczek: So net of your expenses there's a considerable value as a business case for group purchasing.

Mr. Kent Nicholson: Absolutely.

Ms. Helena Jaczek: Thank you. I'll reserve any time.

The Chair (Mr. Ernie Hardeman): Thank you. The opposition: Mrs. Elliott.

Mrs. Christine Elliott: Good afternoon. Thank you again for joining us at committee. My questions primarily relate to your response to Dr. Thiessen's recommendations. I'm specifically referring to your response to recommendation number 3, which indicates that you're going to be working with partners to develop standardized product and service specifications. I'm just trying to understand the scope of that work. Is that for all of the products that you currently have contracts with, the companies for all of the products that are out there now?

Mr. Kent Nicholson: No, the recommendation was specifically targeted at sterile pharmaceutical preparation services, so the 117 products that are under that contract, we would drive to a potentially standard specification: a standard way of preparing those products, a standard way of labelling those products. We felt that we could not wait until all the partners and all the stakeholders rallied around this issue, so we have taken some steps within our own control, between ourselves and Marchese, with our pharmacy committee. But if and when a larger scope, which might include ISMP and the college, wanted to undertake more specificity around compounding activities, of course we would be at the table.

Mrs. Christine Elliott: I'm just trying to understand: Are they 117 different specifications for each product, or is it one standard that will apply to all that you're talking about?

Mr. Michael Blanchard: There's a series of specifications for this type of product. The number that

Kent is referring to is the 117 items that were on this contract, so sterile IV admix products. We're working on developing a set of award criteria.

Mrs. Christine Elliott: Okay. And you also mentioned that in the meantime, until it's all been developed, you've looked at current contracts and you've ensured that all the labels represent the final products precisely. Could you just explain what kind of a process you've gone through to ensure that?

Mr. Michael Blanchard: Well, working with Marchese, several discussions and meeting with them. We've worked collaboratively using Dr. Thiessen's report as a baseline for activity, so reviewing the shelf life, for example; validating, doing a literature search and ensuring that there is evidence to support the shelf life for all these products. Marchese has agreed to visit all the hospitals, bringing in with them their admixing formulas, sitting down with the clinical manager for that particular area, reviewing and obtaining a sign-off from that hospital, acknowledging and attesting that, "Yes, this is the label, the process, in which you're manufacturing the product or putting the product together." I agree with it and I'm aware of it. That's just a couple of examples that we've worked our way through.

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Mrs. Christine Elliott: Has that process been completed for all of your current contracts?

Mr. Michael Blanchard: It's certainly completed by hospitals. They've been making appointments and reviewing. We've also decided to come to some agreement on how Marchese is going to manage and address the overfill issue, for example, on the antimicrobials. The proposed label changes have been agreed to; they have reviewed them—Marchese is actually asking ISMP to review the labels. So we're hoping to get that final feedback from them in the next week or two and implement those changes for the antibiotics.

Mrs. Christine Elliott: You also mentioned—and this is under "Actions taken by Medbuy in connection with the Marchese contract"—speaking about going to the hospitals and meeting with their personnel to make sure that they understand the use of the products that they currently have under those contracts through Medbuy. Who do you typically meet with at the hospital? Is there a—

Mr. Michael Blanchard: Basically we facilitated those meetings by identifying, through our pharmacy committee, the expert pharmacist responsible for delivering that care in the hospital. Marchese's clinical pharmacist and business manager will meet with that pharmacist from that hospital to review.

Mrs. Christine Elliott: Then, I guess, it would be up to the individual hospital, the pharmacy representative there, to disseminate that information to all of the front-line staff. Is that your understanding of the situation?

Mr. Michael Blanchard: Yes—if there's any changes, of course. But to date, there have been no issues that I'm aware of with the current products. If there are any changes to labelling and so on, there is a communica-

tion tool that's prepared and disseminated to all the hospitals. Within the hospitals, there's distribution and communication out to the front-line staff.

Mrs. Christine Elliott: One of Dr. Thiessen's recommendations that I know isn't strictly under your purview was to recommend that the Ontario Hospital Association conduct a formal review to determine the efficiency and traceability of computer-based clinic and hospital records. I'm just wondering about your observations as to how things stand now. What recommendations would you make to that, and what do you think the OHA's recommendations would be in that respect? Is there anything in particular that stands out in your mind that they should be looking for?

Mr. Michael Blanchard: That's one of the recommendations that I needed some clarification on. So I couldn't really comment on it, unless—

Mr. Kent Nicholson: Again, I think we would be working on assumptions. I think Dr. Thiessen saw things in his review at individual hospitals and I think it involved traceability, the ability to actually pinpoint the patients that were impacted. It took varying degrees of time, and that all points to a system that perhaps traceability within the hospital requires a view. I think that's what Dr. Thiessen's recommendation 11 was highlighting.

Mrs. Christine Elliott: It would certainly seem that if we had a working system of electronic medical records, that would certainly facilitate that work and would eliminate a lot of the assumptions that we're working on. We would have that information available in real time. Would you agree with that?

Mr. Kent Nicholson: Yeah. We've spent a lot of time today—actually, a surprising amount of time—talking about barcoding. Again, that is directly linked to traceability within the hospital system. So our committee members who highlighted having a barcode on the label were well placed in their thinking in terms of making this an important criteria. It was a distinguishing factor in terms of why we made the award. Baxter was not in a position to provide products barcoded; Marchese were already there. So it was one of those points of differentiation that had a significant impact on the outcome.

Mrs. Christine Elliott: Thank you. I believe my colleague has another question.

Mr. Jeff Yurek: Reviewing the notes, during the RFP review of the request that came in, there was a huge discrepancy in the price on one of the products, where Baxter was five times the price of what Marchese came in at. Did that raise any red flags? Did any of you call up—either company—and say, "You're way out of whack on your pricing here. Is there an explanation?"

Mr. Kent Nicholson: I think I've heard that you've received some testimony from, perhaps, Marchese and, perhaps, Baxter as well. We are awarding the contract on a total financial submission basis. In this particular case, the two bids in question were very close. Nothing in the overall submission highlighted any type of issue.

We tend not to assess individual line item pricing because we have no basis of understanding how individual companies decide to break down their overall price into individual line item. So, as an example, one company might break down their pricing, really based on a time and motion study and in a very factual way. Somebody else might break down their pricing in a much simpler way—size of bag, as an example. So trying to conclude something from line item pricing is really impossible for us to do.

I think I've highlighted that the two products in question represented less than \$10,000 out of the \$2.6 million that members drew against this contract. Identifying the financial difference in line item pricing at that level was really impossible for us to identify or draw any conclusion.

Mr. Jeff Yurek: With regard to your financials that you give to your members, does that get filtered up to the Ministry of Health?

Mr. Kent Nicholson: Get filtered up?

Mr. Jeff Yurek: To the Ministry of Health.

Mr. Kent Nicholson: I'm not aware whether our—some of our financial information is available in our annual report, which is available online. Again, as an organization, we are uniquely transparent. Our audited financial statements are not found in our annual report. The nature of what we do, because we're not involved in the transaction itself—so the \$627 million you referenced: I'm not party to any of those transactions. I don't order product. I don't receive product. I don't pay an invoice. So, quite frankly, our financial statements are rather boring. Again, it accounts for our operating expenses, and that's about the detail that's contained in our financial statement.

Mr. Jeff Yurek: Do the rebates flow through Medbuy or do they go directly to the hospitals?

Mr. Kent Nicholson: The rebates flow through us. We offset our operating expense. The remainder is distributed 100% to our members.

Mr. Jeff Yurek: So that would—

The Chair (Mr. Ernie Hardeman): Thank you very much, Mr. Yurek. Your time is up.

We have one minute left for the government side.

Ms. Helena Jaczek: Yes, thank you. Just to follow up a little bit on the savings that accrue to hospitals, what do you compare your price to? Is it the price that an individual pharmacy would have to pay for the product if they ordered one dose? Or how do you come to those savings numbers?

Mr. Kent Nicholson: So the reference that I made to what we took out last year and the savings that we generated were against the previous contract, so against what those hospitals were previously paying. Same volumes, same—

Ms. Helena Jaczek: How would you reckon your savings the time you put out your first contract? How would you calculate savings there?

Mr. Kent Nicholson: Well, again, generally if it's an entirely new service never acquired by the hospital

before, we would have no basis to benchmark. The issue of compounding—they, historically, were compounding prior to us being involved in that activity at all, so we would have had a basis of comparison in 2008. We would have had another basis of comparison in 2011, when it went back to market.

Ms. Helena Jaczek: But there's no sort of absolute price that you compare to. It's all based on previous contracts?

Mr. Kent Nicholson: Yes.

Ms. Helena Jaczek: Okay, fine. I want to understand the whole picture.

Now, since you have so many pharmacists, obviously, 25 members, hospitals and so on, one of the recommendations in Dr. Thiessen's report, of course, is to have the Ontario College of Pharmacists have the power to license hospital pharmacies. Have you had any feedback from your membership as to how they're reacting to that?

Mr. Kent Nicholson: I've got a couple here, former hospital pharmacists.

Mr. Michael Blanchard: It's something that the hospital pharmacist community in general are embracing.

Ms. Helena Jaczek: Good. Thank you. No further questions.

The Chair (Mr. Ernie Hardeman): Okay. Thank you very much. That concludes your time.

M^{me} France Gélinas: Chair?

The Chair (Mr. Ernie Hardeman): Yes?

Ms. Cindy Forster: I'd like to move a motion before we recess at 6.

The Chair (Mr. Ernie Hardeman): Let's finish this one first.

We thank you again very much for being here for a repeat performance. Obviously, in most cycles, a repeat performance is that if you did a good job the first time, you get an encore. We'll have to judge to see as to how the rating of the second performance turns out. But thank you very much for being here again today.

With that, I do have a couple—and we'll get to your motion. We were contacted by Dr. Thiessen, our previous presenter. He would like confirming that he has now concluded performing here, and as he mentioned in his presentation, he wants complete—what shall we say?—clearance so he can do other things, that he's no longer involved in dealing with this report. I told the Clerk to contact him and say that, in my mind, he was complete, but if that wasn't so, we would let him know. Is everyone here happy with that? Okay, thank you very much. We can do that.

Now we have a motion.

Ms. Cindy Forster: Thank you.

I move that, pursuant to standing order 111(a), the Standing Committee on Social Policy study and report all matters related to the mandate, management, organization and operation—

The Chair (Mr. Ernie Hardeman): Excuse me. We can table the motion, but you can't really put the motion. As we ruled on the other one, this meeting was set up for

something else. You can table it with the Clerk to be dealt with at the next convenient time.

Ms. Cindy Forster: Well, I'd like to request that that be the first order of business tomorrow at social policy.

The Chair (Mr. Ernie Hardeman): We'll have to see what—the social policy is set up tomorrow for a closed meeting for report writing. We'll have to make a decision at that time as to what we do with it at that time.

We cannot make a motion today to tell what this committee must do tomorrow.

Ms. Cindy Forster: Well, in fact—

The Chair (Mr. Ernie Hardeman): Okay, thank you. That concludes the debate.

Now, is there anything else for the betterment of Rotary? If not, this meeting stands adjourned.

The committee adjourned at 1752.

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